VOLUME 8 NUMBER 10

# Food-Drug-Cosmetic Law Journal

OCTOBER • 1953

**Use of Modern Statistical Methods in Regulatory Activities** . HOWARD L. STIER

**United Kingdom Food Law Problems: Public-Health Hazards and the Analytical Chemist** . . . . . J. R. NICHOLLS

**Some Legal Aspects of the Substitution Problem** . . . . . JOSEPH H. STAMLER

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A COMMERCE CLEARING HOUSE PUBLICATION

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The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need.

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# FOOD DRUG COSMETIC LAW JOURNAL

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# REPORTS

## TO THE READER

### About the Authors

Additional papers presented at the annual meeting of the Division of Food, Drug and Cosmetic Law, American Bar Association, at Harvard University Law School are included in this October JOURNAL. They were delivered by **Howard L. Stier** and **John J. Horan** on the second day of the meeting.

Dr. Stier, director of National Canners Association's Division of Statistics, received his B. S. degree and a special teacher's diploma from the University of Maryland in 1932. After graduation, he worked for two years in the United States Department of Agriculture's Beltsville Research Center. He began graduate work in horticulture at the university in 1935, and received an M. S. degree in 1937 and a Ph. D. two years later. From 1935 to 1939 he had served as a research assistant at the university's agricultural experiment station. In 1939, Dr. Stier joined the faculty of the college of agriculture there and held the rank of assistant professor of horticulture until 1941, when he began active duty with the Quartermaster Corps of the Army with the rank of first lieutenant.

He was discharged in 1946 with the rank of colonel. Dr. Stier's Army assignments included service as chief statistician of the Quartermaster Corps; chief of the statistics branch in the office of the Quartermaster General; and director of the Progress Analysis Division of the War Assets Administration for eight months prior to his discharge. He was awarded the Legion of Merit for his wartime service.

In September, 1946, he returned to the University of Maryland as extension professor of marketing and head of the state department of markets. He held those positions until he joined the staff of the National Canners Association, in 1951, to take the position he now holds.

Mr. Horan is a member of the legal department of Merck & Company, Inc., Rahway, New Jersey. He attended the Sixth World Health Assembly in Geneva, Switzerland, in May as advisor on legal matters to the American delegation and as representative of the American drug and pharmaceutical industry.

A member of the New York Bar, Mr. Horan serves on various committees, such as the ABA Trade-Mark Committee. He is assistant editor of the *United States Trade Mark Reporter*.

As retiring president of the Society of Public Analysts and Other Analytical Chemists, **J. R. Nicholls** addressed that organization's annual general meeting last March 6 on the role of the analytical chemist in combatting public-health hazards. The speech, which appeared in *The Analyst*, journal of the society, is reprinted in this issue of the FOOD DRUG COSMETIC LAW JOURNAL. Dr. Nicholls is deputy chemist in the United Kingdom Ministry of Food.

**Joseph H. Stamler,** New Jersey attorney and counsellor at law, was edu-

cated at Princeton Preparatory School, Rutgers University, Cornell University and Harvard Law School. He holds degrees of A. B. and LL. B.

Mr. Stamler has served as Special Deputy Attorney General of the State of New Jersey, and is presently engaged in private practice in the law firm of Lorentz and Stamler, Newark. Additionally, he is a lecturer in appellate practice and procedure at Rutgers Law School and in pharmacological jurisprudence at Rutgers College of Pharmacy. He spent more than three years in the Air-Sea Rescue Service of the Army Air Force during World War II.

Another research study by a 1952-1953 fellow in The Food Law Institute's New York University program of graduate food and drug law instruction is **John C. Martin's** "Section 403 (d)—Containers So Made, Formed or Filled as to Be Misleading," which rounds out this issue of the JOURNAL.

# In the Food and Drug Administration

**Monthly Report Issued September 22, 1953.**—Sixty-two seizures were made in August of products alleged to be in violation of the Federal Food, Drug, and Cosmetic Act, according to the Food and Drug Administration, Department of Health, Education, and Welfare.

More than 262,000 pounds of the food seized consisted of filthy or decomposed grains and cereal products, butter, eggs, seafood, spices, fruit and vegetables, poultry, and nuts. Eight other shipments of food were seized because of short weight or substandard quality.

Five drug shipments and two lots of devices were alleged to be substandard or misbranded with false and misleading curative claims. One of the devices was a hearing aid, consisting of a piece of wire twisted to resemble a miniature tuning fork, which was to be inserted into rubber discs with perforated centers. Although it was promoted as a scientific marvel of the century and salesmen were instructed to compare it to the miracle drugs, the government charged it was ineffective. The other devices were vibrating mechanical massage chairs claimed to relieve arthritis, asthma, neuritis, sore muscles, aching back, etc., and to improve physical fitness.

**Arrangements with Production and Marketing Administration.**—Working arrangements between the FDA and the Production and Marketing Administration of the Department of Agriculture, concerning their respective regulatory and service activities in the field of food products, have been approved. According to the Memorandum of Agreement Between the Production and Marketing Administration and the Food and Drug Administration Concerning Inspection and Standardization Activities Related to Food Products, approved by Howard H. Gordon, Administrator of the PMA, and Commissioner Charles W. Crawford of the FDA:

"The two agencies have certain common or related objectives in carrying out their respective regulatory and service activities. Therefore, it is believed desirable from the standpoint of public interest to set forth . . . the working arrangements which are being followed or adopted in the interest of each agency discharging as effectively as possible its responsibilities related to the inspection and standardization activities for food products."

It was stipulated that provisions of the memorandum may be modified at any time by mutual agreement.—CCH FOOD DRUG COSMETIC LAW REPORTS (September 21, 1953), ¶ 6615.65.

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# Use of Modern Statistical Methods in Regulatory Activities

By HOWARD L. STIER

**This Speech Was Delivered Before the Division of Food, Drug and Cosmetic Law, American Bar Association, at Cambridge, Massachusetts, August 26**

THE INTEREST of the legal profession in the application of statistical methods is another indication of the progressive and objective thinking that characterizes its members. The Division of Food, Drug and Cosmetic Law is, it seems to me, an especially good forum in which to discuss the effective use of modern statistical methods in legal and regulatory activities.[1] Your intimate contact with industry and management has provided an excellent opportunity to observe directly the extremely effective and increasing use of the statistical method in finding the answer to many kinds of problems.[2] The singular success and greatly expanded use of statistical techinques in recent years is proof of their value and need.

Actually there is a close kinship between the lawyer and the statistician. Statistics is basically the organization and analysis of

[1] The particular interest of this group in the subject is shown by the publication in FOOD DRUG COSMETIC LAW JOURNAL of several articles involving the statistical method. See Kennedy, "Sampling by the Food and Drug Administration," FOOD DRUG COSMETIC LAW JOURNAL (1951) p. 759; Kramer, "An Objective Approach to the Problem of Developing Grades and Standards of Quality," January, 1952 issue, pp. 23-30. See, also, Austern, "Current Developments and Prospects in Canned Food Standards," *Proceedings of the N. C. A. Technical Sessions*, January 20, 1952.

[2] For an excellent discussion of the value and responsibilities of the statistician to management see G. L. Seaton, "The Statistician and Modern Management," 2 *American Statistician* 10-11 (December, 1948).

**Mr. Stier Directs the Division of Statistics, National Canners Association**

facts, while law, in the classical words of Frederick Bastiat, is organized justice.[3] Lawyers, I have been told, instinctively are good bridge players and many are genuinely interested in mathematics. They should also be attracted to statistics if only because that science offers an effective method of using facts for decision and action rather than opinion, conjecture or prejudice. Indeed, as Mueller[4] has said, the use of the science of statistics involves general acceptance of the scientific method which hinges on the use of facts rather than hunches or guesswork. By means of figures statistics depicts activities of all kinds in quantitative terms. Consequently, the *real* magnitude of observed differences is usually more easily discernible.

## Statistical Method Important in Developing Realistic Standards

Many modern statistical applications involve the use of known laws of probability to determine the limits of expected "normal" variation. A sound basis is thus provided for accurately forecasting the probability of occurrence of certain events and the significance of observed differences. Consequently, by means of small samples properly selected it is possible to obtain a precise estimate of the characteristics of the entire group or lot from which the sample was drawn. Even the statistical neophyte will, with some reflection, realize the importance of this mathematical tool in developing realistic and reasonable food and drug standards, as well as in enforcing them.

By properly sampling the production from good commercial practice and the application of statistical analysis to the data obtained,

[3] Frederick Bastiat, *The Law*, first published as a pamphlet in 1850, translated and printed by the Foundation for Economic Education, 1950.

[4] Robert Kirk Mueller, *Effective Management Through Probability Controls* (Funk-Wagnalls, 1950), p. 18.

standards can be scientifically established which are based upon what the men, machines and material involved can actually produce, not upon what someone *thinks* they can produce. The same techniques are equally valuable in determining the *enforcement* procedures for the standard or regulation.

The value of the statistical method in the field of food and drug regulation and enforcement is accentuated today because of the many federal as well as state administrative agencies that are involved. These agencies are today given broad responsibilities, and both the state legislatures and the Congress have delegated to them wide rule-making powers. It is here that we come to the hub of our problem. As Thomas W. Christopher [5] recently stated:

> . . . this granting of authority provides what is probably the most significant problem today in administrative law: How can an agency be given the necessary authority to accomplish the desired ends without that authority being used in undesired ways?

Resolution of that basic question requires not only the education of clerks and of lawyers, but also of business leaders because it is usually business that directly is affected by administrative rule-making. Modern statistical techniques provide the best means whereby facts of a quantitative nature can be assembled and objectively evaluated to prevent misuse of the delegated authority. Their proper use eliminates bias, personal opinion, conjecture and administrative predilection in the formulation and enforcement of regulations, whether by an administrative agency, industry group or any other body.

## Facts Must be in Agreement with Reality

Sometimes, apparently objective facts may not be in agreement with reality. In such instances, it is important that the statistician get the story behind the facts, for unless the layman is satisfied that the facts are in agreement with reality, a doubting eye will be cast upon the statistician and all his works. Seaton [6] effectively points up this type of situation by comparing it with a pencil standing in a glass of water. It appears bent but when felt with the fingers the same pencil is found to be straight. The understanding of these contradictory observations depends upon further knowledge, and understanding beyond appearances. The statistician (or the lawyer) cannot expect to have any statement accepted solely because it is the result of a cer-

[5] Thomas W. Christopher, "Use and Misuse of Authority by Federal Agencies," 30 *Harvard Business Review* (November-December, 1952).

[6] Work cited, footnote 2.

tain statistical analysis. It must first be demonstrated that the conclusion is in agreement with reality.

## Statistical Techniques Now Widely Employed

Much of the modern world's work is being done with the aid of statistical techniques.[7] Statistical quality control is being adopted in the manufacture of many products. Statistical techniques to determine whether shipments and deliveries meet specifications are effectively being employed by the military and by many industrial companies.[8] Thy are essential in biological and agricultural research of all kinds, market research, engineering, applied chemistry, manufacturing, public health, traffic control, communications and, notably, the fields of physics and atomic energy. Theories of sociology, political economy and economics all rest on the statistical method for support. Indeed, H. G. Wells once remarked that statistical thinking may one day be as necessary for efficient citizenship as the ability to read and to write.

Dr. W. Edwards Deming, the well-known mathematician and statistician, recently discussed "Statistical Techniques in Industry as a National Resource."[9] His presentation and arguments were compelling and clear. Dr. Deming made the statement that "the statistician's specialized knowledge is a living, vital, indispensable force today in commerce and industry." One might add that statistical methods should be a vital and indispensable part of regulatory and legal activities.

Dr. Deming made another key statement that warrants quotation:

> Statistical brains is a rare commodity. Management, to meet world competition, should distribute this rare commodity to strategic spots within the company, from raw material to consumer. To use statistical techniques as a tool, management need not know statistical techniques. Management cannot be expected to become versed in statistical theory any more than in physiology, thermodynamics, chemistry, or electromagnetic theory. However, management can learn quickly the rudiments of the statistical ***principles*** of sampling, of the design of experiment, and of the control chart. Management can learn what happens when statistical techniques are applied, and management knows something about conservation of scarce commodities, and the coordination of functions.[10]

Many believe that these comments apply equally to the legal profession and to administrative agencies as they do to the management of industrial concerns. Some have even suggested that an understanding of the use of statistical principles is a prerequisite for lawyers

[7] See "The Statistician and Everyday Affairs," an editorial in the 2 *American Statistician* (October, 1948).

[8] Brown, "Quality Control," 24 *Harvard Business Review* 69 (1951).

[9] Presented before the American Statistical Association at the annual meeting, in Chicago, Illinois, December 27, 1952.

[10] Cited at footnote 9.

who venture into regulatory work, for "statistics like alienists will testify for both sides." [11] There is already considerable evidence of the importance of knowledge concerning the application and use of statistical techniques in the legal profession, and particularly in the field of food, drug and cosmetic regulation.[12]

Kennedy has pointed out the apparent lack of statistical validity in many of the sampling procedures used in seizure cases involving the enforcement of the specific statutory prohibitions of the Food, Drug, and Cosmetic Act. He has concluded that "the cases suggest that some of the courts may have been willing to condemn entire shipments on the basis of evidence which no statistician would regard as satisfactory." [13] Anyone who has had the opportunity to examine the recent *Jaqua* case [14] will have encountered the use by a federal judge of a combination of averages which would appear at least quaint to anyone familiar with statistical methods.

It is in the rule-making area and particularly in the development of food standards under Section 401 of the Act that use of statistical techniques offers so much promise. A member of the Food, Drug and Cosmetic Law Division of the American Bar Association recently pioneered in urging the use of the statistical method and in developing the techniques of application to the standard-making process.[15] I am happy to add that the FDA costarred very willingly and most effectively in this legal effort. It is hoped that this progressive approach to the application of the statistical method will characterize FDA activities in the future. This combination of objective and cooperative action by industry lawyers and the Food and Drug Administration is very fortunate. It develops respect for both the lawyers and the administrative agencies involved and insures reasonable regulations for the affected producers and abundant protection for consumers.

Earlier I indicated that probability is the basis of many applications of the statistical method. Perhaps even more basic to the statistical method is the concept of variability. Unfortunately it is a concept which most of us do not have occasion to learn despite the

[11] F. H. LaGuardia, in *Liberty* magazine, 1933.

[12] For an interesting example of statistical refinement in regulatory work, see the Public Health Service Milk Ordinance and Code (Department of Health, Education, and Welfare, 1953), Part I, explaining the use of logarithmic averages and other methods for determining the grade and condition of milk, and Appendix E thereto, providing methods of determination and logarithmic tables for use by local milk inspectors.

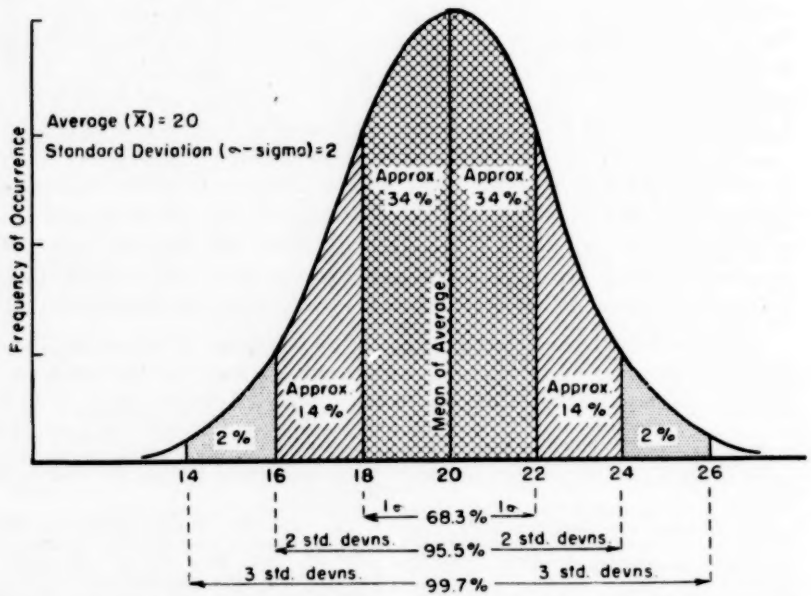
[13] Cited at footnote 1, at p. 767.

[14] No. 51-c-1809, United States District Court for the Northern Division of Illinois, April 22, 1953. The text of the court's findings have been published in N. C. A. Information Letter No. 1435, pp. 176-177 (May 2, 1953).

[15] See Austern, work cited, footnote 1.

fact that it is the woof and warp of our everyday life. We blithely pursue our daily tasks with the mistaken impression that usually there is an exact and precise answer to most of our questions. Perhaps we are conditioned by the early and constant emphasis, throughout our education, on the principles of arithmetic and exact answers to arithmetic problems. The exactness that we learn in arithmetic is largely confined, in our everyday life, to the activities of the accountant and the bank clerk.[16] In practically every other activity, variability is a fundamental quality. This is especially true in biological phenomena. Someone has said that the most invariable thing about nature is its variability. Indeed, variability is inherent in practically everything. If we are not aware of it, then it is because our instruments of measurement are not able to detect it.

Variability, and the laws of probability that enable us to delimit it, underlie the science of statistics. It is the measurement of variability which creates the "distribution" that is inherent in every array of statistical data. When values which vary in a "normal" manner are plotted, we obtain the following type of curve:




[16] For an interesting and more complete discussion of this point, see M. J. Moroney, *Facts from Figures* (Penguin Books, 1952), p. 459.

The figures incorporated in this chart are fundamental to an accurate understanding and use of the statistical method. Anyone who would apply the principles of statistics should always be able to visualize its components. They provide the basis for understanding the significance of observed differences as well as the theory of sampling, both of which are so important in establishing and enforcing food and drug regulations. The average (or mean) provides a measure of the central tendency of any given distribution. The most important measure of dispersion is the standard deviation.[17] Its significance is not always readily recognized by students of statistics. Knowing the average or mean and the standard deviation of a small sample makes possible a relatively precise estimate of the characteristics of the entire group or lot from which the sample was obtained. This can be done because the spread of the values in a sample will be less than for the entire lot from which drawn but will bear a relatively constant mathematical relationship to the spread of the lot or parent population.

## Importance of Randomness

At this point another important concept must be mentioned—randomness. Unless we give equal opportunity for all characteristics to occur in the sample which we draw, we may have a sample which is more or less biased and will give an untrue estimate of the group or lot from which it is drawn. No matter how precise and elaborate might be the physical, chemical or other measurements that we make, if the items in the sample do not adequately represent the lot from which they are taken, we cannot get an accurate picture of the lot. As Dr. Deming has said: "There can be no measurement of the lot unless we can somehow draw a proper sample for test." [18]

Both the possibilities and the problems in the use of the statistical method in regulatory activities have come into *especially sharp* focus in the instance of canned foods where sampling and inspection destroy the portion examined. Consequently, compliance with a regulatory standard must be determined on the basis of relatively small samples from a particular lot. The problem is further accentuated because canned foods, necessarily, are produced at high speeds during the harvesting season, which factor is not conducive to great precision in

[17] The root mean square deviation. For an excellent discussion of the standard deviation and its calculation, see Moroney, work cited, at p. 61.

[18] W. E. Deming, "Some Basic Principles of Sampling," *Quality Control Conference Papers* (1953), pp. 427-434.

filling or uniformity in other characteristics. Wide variations sometimes occur in the raw materials received. Even with small, discrete units like peas, a simple measurement of fill cannot be applied without recognizing that peas shake down after processing and standing. Some vegetables absorb water in processing; others lose it. Differences are encountered in the same product between brine and vacuum packing. Specific gravity varies according to maturity; and differences in porosity or other physical characteristics control the amount of liquid pickup.[19]

It is easy to talk theoretically about volumetric measurement or drained weight or water capacity—it is an almost impossible job to prescribe a meaningful yet reasonable level which will operate in all areas and from season to season on every individual can. Hence the FDA has in practice applied averaging concepts without their being articulated in the regulations. Many have felt that better regulations and more adequate compliance can be achieved by actually developing, in hearings and subsequent findings, both the standard and the method of compliance on the basis of sound statistical techniques.

The use of modern statistical methods in the regulatory field offers a procedure whereby both producer and consumer risks can be accurately determined. Statistical methods decrease and in some instances almost eliminate the need for subjective evaluations and for rule-of-thumb decisions and actions. Obviously, the use of these powerful mathematical tools becomes one for great potential good in regulatory work.

## Use of Statistics in Canned-Pineapple Standards Proceeding

Generalizations, however agreeable, are not often illuminating or persuasive. Let me, therefore, follow the lawyer's technique of giving you a case history—an actual standard proceeding prepared and conducted by a well-known lawyer in the food and drug field who has, to a remarkable degree, accumulated an accurate understanding of statistical methods and an appreciation of the important part they can play in regulatory activities. A quotation from the proposed findings of fact in the pending proceeding to standardize canned pineapple will illustrate my point:

> The interest of consumers can be better served, and reasonable, realistic standards of fill of container that are susceptible of objective compliance and effective enforcement can be administratively developed by the utilization of

[19] Further details are given in Austern, work cited, footnote 1.

statistical methods now widely employed in industrial quality control, testing, government and industrial procurement, and in the evaluation of scientific research data.

Even though it has brought to light a great many problems that have not yet been resolved, this pineapple standards proceeding may become a legal milestone in that for the first time, to my knowledge, modern statistical techniques have been applied to the basic data and developed at a public hearing on a proposed FDA regulation. Perhaps even more important, the proceeding has recognized the inseparable relation between what has developed as the standard and the sampling methods to be used in its enforcement.

This latter point is the foundation for a word of caution for those who would seek to employ statistical methods. They cannot be used in a vacuum. The methods of the statistician must be combined with a practical working knowledge of the commodity and the industrial activity for which the statistical methods are to be used. Recognition of this fact is pointed up effectively in another part of the proposed findings of fact in the pineapple standards hearing. This states:

> An appropriate sampling method, to be employed in measuring compliance with the statistically determined standard . . . must afford a high probability of rejecting a rejectable lot and passing an acceptable lot. Recognition must be given to the practical limits in sampling canned products inasmuch as sampling destroys further salability. In addition to sensitivity, an appropriate plan must permit relative ease of determination by the processor and by official inspection. The accuracy with which drawn samples reflect the character of an entire lot is dependent upon both the size and manner in which samples are taken. Generally the smaller the sample examined the less accurately is the lot portrayed, and conversely the larger the sample the more accurately will it reflect the character of the lot. Practical considerations dictate a maximum sampling of 60 cans in any lot. The method of sampling as specified in Finding 19 is deemed to afford a reasonable balance among all of these factors. It permits lots of clearly acceptable fill to be passed with the minimum number of samples at the minimum cost. It permits acceptance of the lot at any stage of the sampling, but requires larger samples with any lot of questionable character. Finally, it tends to result in lots that are rejected having been comprehensively sampled.

Here we have an excellent statement as to the importance of recognizing the economics, as well as the practical problem, of sampling. Unfortunately, this is a problem that frequently is considered too quickly and passed over without proper consideration and decision.

Statistical techniques are most useful when they are used in a realistic manner. The ultimate in precision and reliability frequently involves too great a penalty in both costs and practicality to be used. When persons (frequently professional statisticians) insist upon the use of statistical techniques without proper consideration of the practical

operating and economic problems involved, the result discourages the use of this valuable, scientific tool. I am sure that every member of the legal profession understands the importance of linking theory and practice in such a manner as to accomplish the most effective use in the application of theory to any field.

## Public Knows Little About Scientific Aspects of Statistics

You are aware by now, I am sure, that I am enthusiastic about the opportunity to utilize modern statistical techniques in the development of regulations and methods for compliance in the field of food and drug regulation. However, the road that must be followed will be tortuous and contain many pitfalls. I would be remiss if I did not point out some of the present roadblocks or what I think may be some of the hazards that lie ahead. Some of the problems of the future will be the direct result of the common misconceptions in the public mind about statistics.[20] Unfortunately, the general public knows little about the scientific aspects of statistics. The average person's experience with statistics is limited to the great mass (sometimes an incomprehensible maze) of government statistics, advertising's special brand of statistics and, especially in times of economic stress, the many charts and indexes that are issued indiscriminately for the avowed purpose of informing the public about the Nation's economic condition. It is this type of usage that Moroney refers to as "Statistics, Undesirable," [21] and which is responsible for much of the popular aversion to statistics, so effectively described by the words "lies, damned lies, and statistics." Perhaps this background may help to explain a statement which recently appeared in the printed report of the Senate Appropriations Committee.[22] The report dealt with the disposition, by the committee, of the budget requests by the Departments of Labor and of Health, Education, and Welfare, and related independent agencies. The following statement appeared on page 7 in that section of the report concerned with the Food and Drug Administration:

> No funds are allowed for *statistical positions to improve sampling techniques* or for additional personnel for investigations into the illegal sale of dangerous drugs without prescription. The request presented to the Committee for the former *was rather amazing* in that the justification offered was that a statistician would advise the inspection force, with years of experience, the amount of sample

[20] For an excellent discussion of this point see Moroney, work cited, at pp. 1-2.
[21] See Moroney, work cited, at pp. 1-3.
[22] Report No. 478 of the Senate Appropriations Committee, dated June 28, 1953.

to extract from a quantity of butter, or wheat or any commodity, to effect a valid test.

Obviously, whoever wrote that statement had very little or no understanding of the methods of statistics and no appreciation of the scientific approach. Perhaps the fault rests with those who had requested the funds in that they did not simply and effectively demonstrate the real value of the statistician and the statistical method.

## Use of Statistical Method Should Be Accompanied by Understanding of Principles and Knowledge of Data

A legal friend often remarks that any man who endeavors to act as his own lawyer has a fool for a client. Any lawyer who seeks to serve as his own statistician may likewise be trapped by his own ignorance. I am not suggesting that in your work the expert statistician must be on top. I am venturing only to suggest that you should keep him constantly on tap.

To the enthusiastic lawyer who would immediately employ all the statistical techniques available, a word of warning may be appropriate. It should be realized early that the mere running of a mass of data through the statistical "mill" does not automatically assure valid conclusions. The simplicity of the "cook book" approach makes it appealing but, for proper use, one must know when to use the recipe for cake and when to use the one for biscuits. Whether the user of statistical methods is a butcher, baker, candlestick maker or lawyer, he must first be intimately familiar with the data if he would use efficiently statistical methods and techniques in their analysis. The lawyer who would use statistical methods and techniques in regulatory proceedings must know without any question the source of his data and the manner in which they were compiled. He must also have a working knowledge of the subject or the activity that is under analysis.

My final point is a corollary of the earlier remark that statistical methods cannot operate in a vacuum. Necessarily, they must be applied with a practical and realistic understanding of the operating facts. But equally important, the application of statiscal methods requires sound information and data abundant enough to be adequate. Information must not only be susceptible to being reduced to comparable form, it must also be reasonably complete and at a minimum sufficient enough to encompass the variables that are important. This suggests that it may be the task of the lawyer in this field not only to learn the

principles of the statistical method and methods that can be employed, but also to convey to his clients the necessity for maintaining records that will enable the job to be done. Only by having adequate information can you insure, to yourself and your client, that the regulations evolved are statistically well grounded and will be fair and equitable in their impact on his business.

Every lawyer concerned with food and drug regulations can and should learn something about statistics as soon as possible. As Moroney very aptly puts it:

> Don't dismiss the subject simply because it calls for thought. Very likely you will find it an excellent substitute for your lack of experience in some fields. Whatever your field of interest or activity, if your work calls for the interpretation of data, you may be able to do without statistics, but you won't do so well.[23]

For the guidance of those who are interested in studying and applying the fascinating techniques of the statistical method, I have listed at the end of this paper some references which I believe you will find not only educational but will also make good reading. Most of those listed do not use, to any appreciable degree, the technical jargon of the mathematical statistician.

As a distinguished physician once concluded a report, I have in this brief summary perhaps told you more than I know about the possibilities in this area. If I have in any degree succeeded in arousing your interest or created some understanding and appreciation of the scientific use of statistics, I will feel greatly rewarded. **[The End]**

## Suggested References

(1) M. J. Moroney, *Facts from Figures* (Penguin Books), Pelican Book A236—an excellent book for the beginner, comprehensive and readable. "Common sense and simple arithmetic" are all that are needed to go through the book. It is highly to be recommended.

(2) Arkin and Colton, *Statistical Methods* (Barnes and Noble, Inc.)—one of the booklets in the "College Outline" series, and a good elementary text.

(3) Croxton and Cowden, *Applied Statistics* (Pitman)—a comprehensive, well-arranged text covering the application of statistics in the business and economic fields.

(4) Charles E. Clark, *An Introduction to Statistics* (Wiley)—an elementary introduction to statistics featuring an exposition of statistical inference.

(5) G. W. Snedecor, *Statistical Methods* (Iowa State College Press)—one of the most widely used college texts. Seven editions have been printed. Examples are principally from the biological-agricultural field. It is a comprehensive text.

[23] Moroney, work cited, at p. 463. The entire last chapter of his book is especially recommended, even as an introduction to your study of statistics.

By J. R. NICHOLLS

UNITED KINGDOM FOOD LAW PROBLEMS:

# Public-Health Hazards and the Analytical Chemist

**This Paper by the Retiring President of the Society of Public Analysts and Other Analytical Chemists Is Reprinted from the Society's Journal, *The Analyst* (May, 1953)**

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BEFORE I ADDRESS you on the subject I have chosen, I propose, in accordance with precedent, to review briefly some aspects of the activities of our society. This can, indeed, be brief, since the annual reports of the council for this year and last give a complete résumé of the ordinary, sectional and group meetings. This record speaks for itself, but it is important to note that council has started the policy of holding ordinary monthly meetings outside London, and these are to be arranged by an appropriate section or group.

Our membership continues to grow steadily and, although the rate of increase appears temporarily to have slowed down, it is interesting to note that our present number is 60 per cent greater than ten years ago, when we just reached the 1,000 mark. Increase in numbers is a balance between new members, on the one hand, and deaths and resignations, on the other. It is inevitable that time should take toll among the older members of a society, but the tragic deaths of Dr. Cox and Sir Jack Drummond are exceptional.

*The Analyst* has maintained its high standard and the last volume was a record in size owing to the inclusion of the proceedings of the First International Congress on Analytical Chemistry held at Oxford last September. The society has received many congratulations on the speed with which the proceedings were published, and credit for this must go largely to Mr. Chirnside, honorary secretary of the congress, and to the editorial staff of this society.

I do not propose to make extended reference to the various committees of the society, but I should like to emphasize how fortunate we

are in having so many people who give so much of their time voluntarily to the work of the society.

It is perhaps not out of place to refer again to the sending of three society delegates to the Twelfth International Congress of Pure and Applied Chemistry in New York. The congratulatory address presented to the American Chemical Society on the occasion of the celebration of its seventy-fifth anniversary was suitably acknowledged by the president of that society.

The second Bernard Dyer Memorial Lecture was given last March by the Honourable Mr. Justice Lloyd-Jacob. The stimulating subject was "Lines of Development."

In the annual report of council there is an item under the heading "Name of the Society." This records developments that have been and are taking place and which may lead to the council proposing a change in the name of the society. The background to these developments was dealt with very fully by my predecessor, Mr. George Taylor, two years ago in his presidential address (*76 Analyst 260* (1951)) and I would recommend you to read this again when the council's proposals come before you.

During his term of office a president sees much behind the scenes, and it is only then that he appreciates who is really responsible for the smooth running of what appears to be almost a machine. I should, therefore, like to pay tribute to the strenuous and devoted work of our honorary secretary, Dr. K. A. Williams, and our honorary treasurer, Dr. J. H. Hamence. With them I must associate the whole of the editorial and office staff.

During the present century there have been significant changes in the work of the analytical chemist. One of the most important of these has been the increasing emphasis placed upon the determination of small quantities of substances. There are two aspects of this. In one, major constituents are determined on small quantities of material, and the techinques of microchemistry have been worked out to such a degree of fineness and precision that micromethods are direct competitors with macromethods. In the other, minor constituents are determined at various concentrations down to the infinitestimal. These minor constituents may be integral parts of the material dealt with and may be responsible for part of its particular properties or virtues. On the other hand, they may be adventitious, that is, nonessential additions or materials accidentally picked up. Some of these may introduce a

health hazard, and it is because of this that the determination of the amounts present has become of primary importance.

Any legislative control to minimize such hazards must be founded on medical and pharmacological advice, but it is the chemist who will be called upon for evidence to enforce such control, and his general knowledge—on the one hand, of the materials likely to affect human beings and, on the other, of the needs of industry—enables him to advise on the reasonableness or otherwise of any measures proposed. Hence, the members of this society, whether public analysts or other analytical chemists, must play a prominent, and even leading, part in all public-health matters.

The risks from small quantities of particular substances comprise only part of the public-health hazards. Of recent years a problem has arisen, generally known as chemicals in food, and the adequacy of existing legislation as a protection against possible hazards from substances used in relatively substantial amounts has been questioned. In this country there have been several meetings at which the subject has been discussed and different points of view of the various interests have been ventilated. But the public may be affected by chemicals in other commodities besides food, and in 1949 the Advisory Council on Scientific Policy was asked to examine the existing departmental arrangements for controlling the use of potentially toxic substances or processes in the preparation of various kinds of consumer products. An Expert Committee on Toxic Substances in Consumer Goods was appointed under Professor Zuckerman, and the recommendations of this committee were considered by the advisory council, together with the views of the Medical Research Council and of the government departments concerned. The conclusions are given in the Fourth Annual Report of the Advisory Council (1950-51, H. M. Stationery Office, Cmd. 8299) and may be briefly summarized as follows:

(1) The risk to life and health owing to the presence of toxic substances in consumer goods is probably small, but the rapid growth of the chemical industry and the needs of industry in general are accelerating the pace at which new chemical substances are being introduced into consumer products, and the machinery that exists for testing the possible harmful effects of these substances is inadequate.

(2) Government departments should acquire information about possibly noxious substances or processes that industry may contemplate

using before they are allowed to find their way into the composition or treatment of the articles concerned. New legislation need not be introduced at present. Manufacturers should be informed that they are expected to take all reasonable care to ensure that no new substances should be offered for sale for use in consumer goods if toxic effects are suspected.

(3) A standing committee should be set up in order that there may be a central organization to which government departments can turn for advice.

(4) The Medical Research Council should keep the whole problem of toxic substances under review and should initiate research.

(5) Information over the whole field of toxic substances should be interchanged with appropriate authorities in other countries, particularly in the United States.

This policy is likely to be generally approved, but there may be differences of opinion as to how it should be implemented. Several government departments may be concerned in obtaining the information about noxious substances, and there may be a tendency to deal with certain aspects of the problem piecemeal, action being taken against a particular hazard that seems of immediate importance. This is unlikely to be satisfactory, as reasonable protection should be envisaged and applied before a possible danger shows signs of becoming an acute reality. The measures proposed to minimize one risk must be equally applicable to many others, and all should be considered together.

I should like to put before you my views on how the policy should be implemented, and as there are a few risks that may arise from sources other than consumer goods, I propose briefly to survey the whole field of public-health hazards before indicating how the general problem might be tackled, as far as possible within the framework of existing legislation. I shall not consider industrial hazards, as these are more appropriate for particular treatment and, in themselves, are essentially medical questions.

## Survey of Public-Health Hazards

Public-health hazards may arise from (1) air; (2) water; (3) food; (4) clothing; (5) cosmetics; and (6) household materials.

*(1) Air Hazards.*—Human beings are continually exhaling carbon dioxide, and the amount in the air is augmented by the burning of all types of fuel. In view of the vast extent of the atmosphere and the capacity of vegetation to utilize carbon dioxide for photosynthesis, the normal hazard from this gas is negligible. There are, however, other polluting substances that arise from the combustion of fuel, including unburned and partially burned coal dust, ash dust and grit, coke particles, tarry soot and gaseous sulphur dioxide. Much of this is fine, particulate matter conducive to the production of fog. During this last winter there were periods when fog prevailed for some days, and excessive and unexplained fatalities occurred to human beings and animals. Some medical authorities were of the opinion that local and unusual concentrations of carbon dioxide and other contaminants could not be excluded as a possible cause, even if only contributory. Whether or not this is correct, it is possible that traffic congestion in busy streets may produce a hazard over and above those mentioned, as the exhaust gases from car engines include, in addition, carbon monoxide and the products of pyrolysis of oils, with their increasingly varied additives. The exhaust fumes from factories contribute in a similar way, and while national and local authorities take appropriate measures if there is a nuisance, the aspect should not be overlooked that there may be a public-health hazard. Particulate matter in the atmosphere, not sufficient to cause a nuisance, may settle as dust and subsequently be blown about to be inhaled. These particles, no doubt, remain in the lungs after breathing.

*(2) Water Hazards.*—Water authorities are very conscious of their responsibility to supply a pure article. They make sure that no contamination occurs in their plant or filter beds. But the water comes from a large catchment area and there is always the possibility of contamination either of the natural sources or from polluted areas. We know that certain waters contain high proportions of fluorine, and although the effect of this has been described as only a cosmetic blemish, there are pathological effects if the amount of fluorine is too high. The complete absence from very pure water of certain trace elements, such as iodine and fluorine, may raise the question of deficiencies, for which counter measures may be necessary. This is so closely connected with public-health hazards that it must be considered with it.

The general problem of water pollution is a wide one and goes far beyond my present survey. But there are many ways in which the public health may be involved and this aspect must not be lost sight of. Special problems may be created by the more widespread occurrence of radioactive elements.

*(3) Food Hazards.*—As already mentioned, food is a potential source of many hazards and these may be divided into a number of general classes.

**(a) Metallic contamination.**—The possible dangers from poisonous metals are well known, and good commercial practice tends to reduce amounts present to negligible proportions. One has to consider not only the quantity present in a particular food, but also that which may be present in the complete diet, as absorption of some metals is cumulative. For this reason it is desirable that steps should be taken to reduce the quantity of a poisonous metal present in any one food to the lowest commercially practicable amount. With very poisonous metals, such as arsenic and lead, ordinary commercial practice may not be the best possible to eliminate risks of contamination, and the ideal should be that of the most up-to-date and well-equipped producer. There is a consensus of opinion that the plant used in preparing food for sale should not yield harmful metals to food. Lead pipes should not be used for conveying liquids such as beer and cider. This has been recognized by the trade, and it is largely the difficulty of obtaining replacements during recent years that has prevented their abandonment. It can be hoped that this hazard will be removed within a reasonably short time. Cooking utensils for household use should not contaminate food. Reputable manufacturers are aware of the possible danger, but it is doubtful if our present legislation is adequate for the necessary control.

**(b) Bacterial contamination.**—For manufactured foods this is essentially a matter of hygiene, and good commercial practice results in a negligible risk. Some foods eaten raw, such as salad crops, may be grown on land treated with fertilizers or compost made from sewage sludge, and this may entail a risk.

**(c) Extraneous matter.**—Foods are subject to contamination by rodent residues, insects and mould at all stages of their history. This contamination is minimized by proper hygiene and good commercial practice, but as such matter is largely avoidable, some control may be necessary.

**(d) Wrapping materials.**—Prepacked food comes in contact with a variety of packing materials, and these should not contribute harmful substances to food. Suitable metal foils and plastic materials are known and recommended, but it must be remembered that not all plasticizers and breakdown products of plastics are harmless.

**(e) Insecticidal residues.**—This is a very difficult problem, whether considered from the point of view of the chemist or from that of public health. It may be essential to use insecticides to obtain the maximum supply of natural foods, and it may be inevitable that traces remain in the food that reaches the public. Very potent insecticides have recently been developed and it may be economically essential to use them rather than less dangerous ones. This may be an instance where we are obliged to take a risk, but we ought to know how much remains in the food, what is the fate of the excess used and the nature of any decomposition products. A balance will have to be drawn between economic necessity and possible dangers. If it is essential to accept a risk, the extent of that risk should be known with some degree of exactitude.

**(f) Chemicals in food.**—Here I shall deal with chemicals that are deliberately added for what may be called technical reasons, and I am using the term "chemical" in its widest sense. First, I should emphasize that improvements in food technology should be encouraged in every way, as they help to make the best use of the world's inadequate food supplies. Many alarmist statements have been made about the addition of chemicals to food, and most of these are generalizations from particular and exceptional examples. Hence they must be severely discounted, but they cannot be ignored. All reasonable people agree that the addition of either natural or synthetic chemicals to food may involve a risk to the consumer if there is inadequate knowledge of the pharmacological action of the chemical. Synthetic chemicals as a class cannot be regarded as potentially more toxic than natural ones, for some of the most dangerous poisons are isolated from natural material. It would be completely unreasonable to forbid the use of all chemicals in food manufacture; each must be considered on the information available. But I would suggest as a general guide that if a chemical has little or no food value, it should not be added to food if there is any doubt of its harmlessness and only then if there is justification for its use. Now it is very difficult, if not impossible, to prove that a

substance is completely harmless. What can, however, be done, is for pharmacologists to lay down what tests should be carried out to obtain information upon which an opinion can be based. As knowledge increases, the criteria and tests may need to be revised. This increase in knowledge may have to be sought deliberately by planned research as recommended by the Zuckerman Committee. An important point will be upon whom shall lie the responsibility for carrying out the tests laid down; this I shall come to later, when I make suggestions as to control.

Assuming that tests are prescribed and the responsibility for carrying them out has been localized, I foresee no practical difficulty with such substances as antioxidants, emulsifying agents, antistaling agents and preservatives, as they are relatively pure substances of simple constitution and their numbers are not likely to be great. The position is not so simple if there are many substances of a class, any one of which may be used, and particularly when the members are of widely varying and complicated chemical structure. What I have in mind is food colors, and I must spend a little time in discussing them. These are used legitimately for improving the appearance or attractiveness of foods and, as they are used in quite small proportions, it may be suggested that the risk from them is negligible. This is not so, as we are all aware that certain colors are dangerous and some are already prohibited for use in food. The prohibition of these colors was made over 25 years ago and it cannot be accepted that these are the only ones that are harmful. Synthetic colors are usually made by coupling intermediates that in some instances are known to be toxic. Some of these intermediates are closely allied in constitution to substances that have been proved to be carcinogenetic and we do not know if they are reformed in the body by breakdown of the color. What happens to the characteristic linkage of the azo dyes during their passage through the body? How much of the color is broken down and what are the resulting products? Is the body capable of removing sulphonic acid groupings? These are all questions that ought to be answered at some time. Meanwhile, no color should be used in food if there are serious doubts as to its harmlessness. Manufacturers would still have a wide choice of colors that are not suspect in our present state of knowledge, and many additional shades can be produced by appropriate blending. The special action that may be necessary for controlling colors used in foods will be dealt with later.

A new development of recent times concerning the presence of chemicals in food is the specialized use of certain drugs in the breeding of poultry and animals for human food. Stilbestrol is used for the tenderization of poultry flesh and this involves the slow absorption of the drug by the birds over a long period. The unabsorbed drug is removed when the head and neck are cut off before the bird is sold to the consumer and, although the practice may result in the production of more marketable birds, what of the affect, if any, on the consumer of the meat? Antibiotics are used for increasing the rate of growth of pigs. The action appears to be rather the prevention of a depression of growth by specific action on the gut flora, and there may be a risk of the appearance of resistant strains, so that more and more of the antibiotic is required, with subsidiary effects not now apparent. Apart from the probably small risk to the public of normal use in this way, there is clearly a possible danger in placing powerful drugs in the hands of poultry breeders and stockfeeders.

*(4) Clothing hazards.*—The risks from clothing are few, but the effects of dyes, particularly in furs, must be considered. Furs are also sold permanently mothproofed, and this involves the retention of chemicals that may be in contact with warm skin for several hours. Special detergents are sold for washing undergarments, and a property that makes a good advertising point is that no rinsing is required. The washed article, therefore, contains small but significant amounts of substances that remain in contact with the skin for many hours, with the possibility of absorption. Optical bleaching agents for white garments depend for their value upon substances remaining in or on the article treated, and which remain after washing. Although some of these substances are claimed to show their effect after repeated washings, and therefore must be very insoluble, there is no guarantee that absorption does not take place when in contact with the skin and perspiration. Crease-resisting agents are incorporated in some fabrics. These are likely to be made up into external garments, but the material may be in contact with the skin.

*(5) Cosmetic hazards.*—This country has no special legal control over the ingredients of cosmetics, and it does not seem sufficient protection to the public that anything can be sold for application to the external surface of the human body without consideration being given to the possible harmful effects. While we can assume that no manu-

facturer would include in his preparations a substance known to be harmful, can we be certain that all the substances used are, in fact, harmless? If there is a hazard, it is likely to affect nearly half of the population of most countries. What of the purity of the dyes and colors used? These are applied regularly—in some instances in considerable amounts—and consideration must be given to their effects.

*(6) Household hazards.*—A variety of substances are now being sold as household detergents. They are very suitable for the purpose, but one of their characteristics is a tenacious adherence as a surface film on the article cleaned. They are so efficient that little rinsing appears necessary. The amount remaining after wiping may be minute, but there must be an accumulation on the drying cloth used and this may mean that no household plate, dish or glass is completely free from these powerful surface-acting agents, and significant amounts might remain on the crockery of catering establishments. Many of these detergents contain in addition a foaming agent, which contributes to the efficiency of the cleansing action. These foaming agents pass into sewers and rivers and if there is a sufficient accumulation, patches of foam may collect and remain for days. While this is normally only a nuisance, there may be instances where water is drawn from a river for subsequent household use and filter beds may be incapable of removing the foaming agents. To remove the effect of the foaming agents in effluents other chemicals have been proposed, and the addition of these may bring other problems.

Detergents and foaming agents are also used in shampoos, and here an incidental and unsuspected hazard has recently arisen. When hair is shampooed the liquid may run into the eyes, and irritation and slight damage has been caused by certain preparations.

There are some minor household hazards, such as the risk of children sucking toys colored with soluble paint, which need not be dealt with except to say that it might be desirable if powers existed for their general control.

## Control of Public-Health Hazards

Having considered the whole field of public-health hazards somewhat comprehensively, but certainly not exhaustively, I should like to give my views of the sort of control I think necessary, bearing in mind the policy outlined by the advisory council. On principle the people of this country do not look kindly on controls, and this is a worthy

attribute that should be encouraged. On the other hand, there is little antipathy to controls that are proved necessary. Everyone is agreed that where people cannot protect themselves some controls are necessary, and rarely is a voice raised against any reasonable measure to ensure public health.

The various hazards to which I have referred can be broadly divided into three classes, namely, (1) hazards due to lack of hygiene; (2) hazards due to contamination; (3) hazards due to "chemicals," using that term in the widest sense.

*(1) Hazards due to the lack of hygiene.*—These are preventable or largely minimized by proper hygiene and are almost negligible with good commercial practice. In the household, control is the concern of the housewife, and education and common sense are sufficient safeguards. As regards food for sale to the public, we already have legislation to cover the cleanliness of food, and government departments and local authorities have power to make any regulations in respect of places where food is prepared. Reputable manufacturers are little concerned with such control, as their domestic standards are generally higher than any officially prescribed minima.

*(2) Hazards due to contamination.*—These arise from traces of material unavoidably present even with good commercial practice, such as metallic contamination, or from substances remaining as traces after legitimate use for other purposes, such as insecticidal residues, or from substances permitted to be added in particular instances, such as preservatives. For these, statutory tolerances are appropriate, and as regards food, powers exist under public-health or food acts to prescribe such limits. Similar powers would be appropriate for cosmetics and any other consumer goods liable to the hazard. The Atmospheric Pollution Research Committee concerns itself with obtaining data on air contamination, but possibly rather more on the side of the prevention of nuisances than that of hazards; these two aspects clearly overlap.

At the present time the Food Standards Committee of the Ministry of Food has a subcommittee dealing with metallic contamination of food, and several reports have been published with suggested tolerances (copper, M. of F. Bulletin No. 611 (1951); arsenic, M. of F. Bulletin No. 616 (1951); lead, M. of F. Bulletin No. 628 (1951); tin, M. of F. Bulletin No. 685 (1953)).

The Minister of Agriculture and Fisheries appointed a Working Party on Precautionary Measures Against Toxic Chemicals Used in Agriculture, and its first report was published in 1951 (H. M. Stationery Office, Code No. 24-190). This working party was subsequently asked by the ministers concerned (Joint Announcement by the Ministry of Agriculture and Fisheries, the Ministry of Health, the Ministry of Food and the Department of Health for Scotland (June, 1951)) to inquire whether any risks arise, from the point of view of the consumer of the final product, in the use of toxic chemicals in agriculture and in the storage of food, and to make recommendations for protective measures should these appear to be desirable. No report has yet been issued.

It is in connection with hazards due to contamination that our society can play a most important and essential part. Any tolerances allowed must be capable of being enforced and it is the chemist who must develop the methods for determining all the contaminants, and he is likely to be more and more called upon in connection with insecticidal residues and the like.

*(3) Hazards due to chemicals.*—These arise where the harmlessness of the chemical has not been proved, and here statutory tolerances are, in general, inappropriate; either the chemical should be permitted or its use should be forbidden. At present, powers exist for forbidding by regulation the use of a substance in food if it is known to be harmful. But the position as regards other consumer goods is not so clear.

In general, all sales are subject to the Sale of Goods Act, which requires any article sold to be reasonably fit for its normal purpose. The emphasis here is on fitness for use rather than the possibility of a hazard; even where there is a risk, the idiosyncracy of certain individuals may be raised as a defense. Other acts—for example, the Factories Act and the Petroleum Acts—have some bearing on public health, but they are really more concerned with particular dangers and with nuisances. The Public Health Acts and the Food and Drugs Act have already been referred to, and government departments and local authorities have powers to make regulations and bylaws under various acts.

Whatever control measures are envisaged, it seems generally agreed that provision must be made for periodical review. This can be achieved only by a permanent body such as was recommended by the Zuckerman Committee and approved by the advisory council.

The idea of a permanent or standing body is not new. The Pharmacy and Poisons Act, 1933, established a Poisons Board, and we now have 20 years' experience of its working. The board meets periodically and considers what control is necessary over the sale of poisons to the public. The board's recommendations are reported to the Home Secretary, who considers them, and if he thinks fit makes regulations that are laid before Parliament, and to which objection can be raised. If necessary, control action can be taken very rapidly and can equally quickly be amended. I do not think that any objection has been raised to any action that has been taken as a result of the recommendations of the Poisons Board, and this confirms my earlier statement that no objection is taken to reasonable controls designed solely to protect the public.

The standing committee should cover the whole field of public-health hazards and there should not be difficulty in defining its relation to the authorities that now are responsible for some form of control. A new function would be the consideration of those hazards arising from chemicals whose harmlessness has not been reasonably proved. This is an important problem and, as it is likely to become of increasing magnitude, the earlier it is considered the better. It is also a very controversial problem, especially as regards food. I propose, therefore, now to consider chemicals in foods, being sure that hazards from chemicals in other materials can be fitted in on similar and easier lines.

Our present laws make it an offense to add any substance to any food so as to render the food injurious to health. There is little direct evidence on the matter, but it is thought to have worked reasonably well in the past, and many people would like the position to continue. Some of us, however, consider that the time is rapidly coming, if not already here, when we must go a little further. Manufacturers of food are continually looking for some substance that will perform a particular function in improving their products, and chemical manufacturers are often able to supply something that will do the job. New chemicals may be found to have particular properties that could be useful in improving food, and the makers will doubtless advocate their use for that purpose. All these are legitimate objects and make for technological progress. But the substance chosen for use may be quite different in composition from any normal ingredient of food, and its fate and effect in the human body may be quite unpredictable. Con-

sider the recent history of mineral oil in food. Such an oil has been taken internally as a medicine by many people in large amounts for long periods, and when of pharmaceutical quality it might have been presumed to be perfectly harmless as an ingredient of food, for which it is an efficient emulsifier. Recently it was found that in an emulsified form mineral oils seriously affect the absorption and utilization by the body of some of the vitamins and provitamins, with the resulting possibility of deficiency effects. A further risk with such oils is that impure grades have been found to contain carcinogens, and once an oil has been added to food it is difficult, if not impossible, to ascertain the grade used. For these reasons restrictions were placed by order on the use of mineral oil in food. At the time the order was made there was no extensive use in food, and in consequence few manufacturers were affected and little dislocation of trade occurred. It might happen, however, that a particular substance was used on a large scale before it was found to be harmful, and any sudden embargo on its use might cause considerable trade embarrassment. An example to illustrate this point is that of nitrogen trichloride (Agene) used for treating flour. This substance had gained very widespread use before it was discovered that the treated flour contained about two parts per million of a potentially toxic substance, methionine sulphoximine. This substance produced substantial physiological effects in dogs, rabbits and ferrets, but the amount that might be consumed by a man in a year is extremely small and may well be within the ineffective dosage range. The only difference between the protagonists for and against the use of nitrogen trichloride is whether the margin of safety is wide enough. It might, however, have been found that the treated flour was definitely harmful to man, in which event the question of banning its use might have been acute. But what was found was that neither its harmlessness nor its harmfulness to man was proved; nevertheless it is pertinent to mention that when an officially appointed committee reported in 1950 on improvers in flour, the Ministry of Food, the Ministry of Health and the milling industry accepted the recommendation that it was desirable eventually to discontinue the use of nitrogen trichloride and to use chlorine dioxide instead.

In considering any action to be taken on chemicals in food, a case can be made out for making a distinction between those that are already in use and new ones that might be suggested for use. To deal

with the latter first, I would maintain that it is reasonable to insist that all new substances should pass appropriate pharmacological tests before being used for purposes that might otherwise involve a possible public-health hazard. The responsibility for carrying out those tests should, in my view, rest upon those who make the article for such use or upon those who wish to use it for that purpose, or upon both.

In fixing this responsibility, I have in mind two facts. The first is that for many years it has been an offense to add any substance to any food so as to render the food injurious to health. This principle should, I think, apply to all consumer goods. The second is that if a person is charged with unlawfully using a harmful substance, he has the defense that he did not know, and could not with reasonable diligence have ascertained, that it was harmful as used. This is a protection to him, if not to the person harmed. I think the time has come to regard reasonable diligence as including the necessity of testing pharmacologically any novel substance to be used in or on the human body.

As regards the tests to be applied, it should be the responsibility of the standing committee to issue them and to assess officially the results obtained. In doing so, the relative pharmacological effects of the substance should clearly be related to the amount that is likely to be taken. Professor Frazer has suggested (12 *Endeavour* 43 (1953)) that dosage levels can be classified as ineffective, effective, toxic and lethal, and with man the general ratio of these is approximately 1:10:100:1000. He suggests that an acceptable dosage level of a chemical to be used in food should be one tenth of the ineffective dosage level, calculated as milligrams per kilogram of body weight. He, therefore, arrives at the following table:

| Dosage group | Result | Approximate dose relationship |
|---|---|---|
| Lethal | Death | 10,000 |
| Toxic | Demonstrable tissue damage | 1,000 |
| Effective | Significant modification of structure or function | 100 |
| Ineffective | No significant modification of structure or function | 10 |
| Acceptable | ——— | 1 |

He is satisfied that pharmacologists can specify appropriate short-term and long-term tests on different species of animals which would enable noncumulative dosage levels to be assessed.

It is known that several of the big organizations making food additives in this country recognize their responsibilities and carry out tests on these lines. It is desirable that such tests should be standard-

ized and officially prescribed; clearly the right time for them to be carried out is before the substances are used and not while they are being used. It is not a new principle to apply special control to new substances. The Dangerous Drugs Acts place an embargo upon the manufacture and trade in certain drugs not known before a particular date; when satisfactory evidence is produced, the restrictions on a particular drug can be relaxed by order.

When considering pharmacological properties, it is necessary to refer to carcinogens, because everyone is in agreement that no potentially carcinogenetic substance should be added to food. But here a difficulty arises: We do not always know when a particular substance has this characteristic. At a recent meeting on the apparently increasing incidence of cancer in modern times, it was stated that after affection of a person by a carcinogenetic substance a latent period of up to ten years may elapse before any effects are noticed. Once the body has become affected the process cannot be halted, and it may be years before any detection is possible, so making uncertain the possible cause. Any substance, therefore, that is reasonably suspected of possible carcinogenetic properties should be excluded from food.

There remains to consider what action, if any, should be taken with respect to chemicals at present in use. These, I think, should be reviewed by the standing committee, and an official pronouncement made regarding those for which there are reasonable grounds for doubting their harmlessness. All others should be tentatively permitted, but should be reviewed if evidence becomes available of possible risk. In some instances it might be desirable to take steps to ensure that positive evidence is available upon which a review could be made. At the present time certain research associations are examining some classes of products, but the whole field needs covering and this can best be done under the general direction of the standing committee so that no hazard is overlooked. In certain instances it might be appropriate to prescribe the purity of the substance used.

I will illustrate the suggested action by examples of two types of chemicals. The first is artificial sweeteners. For many years there has been a need for such substances, and two found favor in this country, namely, saccharin and dulcin. Neither of these was thoroughly tested toxicologically until recent years, but the results of extended tests have now been published. For saccharin there was no evidence that it was

in any way harmful, at any rate in the maximum amounts ever likely to be consumed. Dulcin, however, showed harmful effects in different species of animals at certain concentrations and under specified conditions. If the standing committee were in existence, it should review the evidence and decide whether it justified banning the use of dulcin. Such a pronouncement, whether for or against, would be of great value to the public and to industry. There are other artificial sweeteners that have been proposed for use, for example, P 4000, and as far as this country is concerned they may be regarded as new chemicals. P 4000 was advertised abroad as completely harmless to humans. The tests used to justify this statement were not disclosed, and many people were chary of accepting the assurance on the grounds that a substance containing nitro-groups and which, at high concentrations, was a local anaesthetic must be subjected to unequivocal tests before its use could be permitted in food. Later, more extended tests were carried out in the United States, and harmful effects were produced in animals. This shows the importance of prescribing the tests to be employed. Under my suggestions, P 4000 would not be permitted for use in food until the standing committee had reviewed the results of adequate tests.

The second illustration that I should like to give is that of food colors. I have already mentioned some of the hazards that might occur from their use and the lack of complete knowledge of their fate in the human body. A subcommittee of the Food Standards Committee is dealing with preservatives, etc., and this includes food colors. This subcommittee has not yet reported and the nature of any recommendations that may eventually be made cannot be presumed. It is, however, carrying out in a limited field the functions that I think the standing committee should perform for the whole of the field. Without anticipating any conclusions of this subcommittee, I will illustrate how food colors fit in with my general picture.

Some hundreds of synthetic food colors are or have been used for coloring food. They are produced by chemical reactions from intermediates, some of which are known to produce toxic effects. For this reason color manufacturers take particular care to supply for use in food those that are as pure as possible and free from harmful impurities. A certain amount of pharmacological work has been carried out on some of these colors over many years and in many countries, but the results of such work can be applied only to a color conforming to

the specification of the sample tested. Some of the colors used in food are produced in less pure grades for purposes other than food and, in order to avoid any unnecessary risk, it is important that a color permitted for use in food should conform to an appropriate chemical specification. This can only be achieved by defining that specification, and this leads to the conclusion, as I think inescapably, that a list of permitted colors is essential, each with its definite chemical specification. At present our law specifies a short list of prohibited colors, and any color not on that list may be used in food, unless its use can be challenged under the Food and Drugs Act. If it should be thought proper to protect the public more fully from a risk that might arise from harmful colors, then inevitably the policy must be changed to a permitted list specifying those colors that, after examination of the evidence, are considered suitable for use. It should be the function of the standing committee to compile this list from the colors now in use having regard to the pharmacological evidence available. No new color should be added to the list without having been adequately tested and approved, and any color on the list found to have harmful effects should be withdrawn at once or, according to the risk, after a specified time. Provision could easily be made for notification of intention and an opportunity given for commercial interests to express their views.

Colors in cosmetics should also be under review and there should be legal powers of control. This, I think, would be accepted by industry, as it would provide a protection for manufacturers from a risk that, although small, is ever present as a civil liability to them.

The field that I have attempted to survey is a large one, and difficult because it is concerned with a great number of risks, most of which, in themselves, are relatively small. Taken together they cannot be ignored, and the public is entitled to expect that consideration will be given to its protection. I hope that my survey will help to give a picture of the whole field and that what I have suggested is a rational, realistic and reasonable implementation of the policy of the Advisory Council on Scientific Policy. **[The End]**

# Some Legal Aspects of the Substitution Problem

By JOSEPH H. STAMLER

**Who Is Primarily Guilty—the Imitating Maker Who Places the Instrument in the Hands of the Substituting Retailer or the One Who Makes the Fraudulent Sale to the Consumer?**

WHEN confronted with vexatious problems which arise in industry, trade or profession, it is difficult to segregate legal liabilities and legal obligations from social, ethical and moral obligations. It is all the more troublesome to confine oneself to the legal implications when tortious misconduct, born of fraud and deceit, is the basic evil. "Substitution" may be so characterized. Therefore, at the outset we must consider how substitution breeds.

There are manufacturers today operating in unsanitary workrooms and steaming cellars, and behind drawn shades. The result of their efforts is the production of a counterfeit product—an inferior make of a product to be offered to the consumer when the well-known brand is sought. These sometimes clumsy, sometimes apish imitations are offered to the retailer at a lower cost than the products carefully manufactured after relentless and extensive research in commendably wholesome conditions of manufacture under elements of ever-watchful control and painstaking care previously unknown in industry or profession. The tawdry counterfeiter in most instances requires the distribution of its counterfeit product in the market place, and this distribution is supplied by the avaricious and greedy retailer who joyfully accepts the cheaper product of the counterfeiter and delivers it to the consumer in the place and stead of the product requested or prescribed. The trusting consumer is purposely deceived; the consumer is systematically defrauded.

**The Author Is an Attorney and Counselor at Law, Newark, New Jersey**

The seller of the product, in most instances, dispenses a cheap, make-shift imitation at the price of the genuine article. The genuine article in some instances may cost the retailer a little more than the imitative product, but the genuine article is supported by research and development with attendant predistribution failures and renewed scientific investigation until—for the first time after great expenditures of money, time and effort—the genuine product is ready to be marketed.

More vividly apparent does the deceit and fraud become when drugs and medicinal preparations are the products involved. The imitative brand which is palmed off to the customer contrary to the expressed instructions in the prescription of the doctor may have come from a manufacturer whose bathtub and basement controls fail to assure the consumer and his physician of proper strength and purity.

The manufacturer of the genuine article now passes on to the doctor the details which will properly support the promotional activities in the distribution of the drug or medicine. The doctor, by virtue of the detail information given by the manufacturer, becomes aware of the therapeutic values and the therapeutic limitations; the idiosyncrasies which may result from the use of the drug; and the cautions and the warning signals with which the physician should be armed. Not so with the imitating manufacturer whose parasitical desires are satisfied with advertising directly to the retailer without any information except that the imitative drug may be used as an adequate substitute for the genuine.

Well-known to the medical profession are the varied reactions of two products containing identical ingredients. Fewer side effects may

result from minute differences. The enteric coating of one product may be the determining factor as to whether the full and complete therapeutic value of the medicinal preparation will be received by the patient at the proper time as desired by the physician. This may be so even though the product is in full strength as far as the active ingredient is concerned.

When the physician has prescribed brand "A" and the prescription has been filled with brand "B," the physician, noting too early or perhaps too long a delay in his patient's reaction to the drug, will be led to believe that brand "A" was not all that it was said to be and may now prescribe brand "C," all to the patient's detriment.

Not too many manufacturers have had the unhappy experience of causing a recall of their product either voluntarily or through government intervention. But how much more difficult then does it become when the physician advises the manufacturer of brand "A" of an unexpected, uncalled-for reaction from what he thinks was brand "A" when in reality brand "B" had been passed off. From the conniving cheat who has profited by the substitution, the physician and the manufacturer cannot expect an admission of guilt.

## Determination of Primary Guilt

At whom is the finger of guilt to be primarily directed—the imitating manufacturer who places the instrument of fraud in the hands of the substituting retailer or the one who makes the fraudulent sale to the consumer?

First, it would be well to examine the nature of the cause of action. "Substitution" has been defined in many ways by many courts. Generally it is described as an act of unfair competition wherein a dealer "passes off" his own or the product of another in the place of the specific brand called for by the purchaser.

The act of substituting has been defined as "beguilement," "counterfeiting," "connivance," "misrepresentation" and by many other vividly apt and descriptive phrases. Judge Forman of the United States District Court for the District of New Jersey in *Smith, Kline & French Laboratories v. Clark & Clark*, 62 F. Supp. 971, at 997 (1945), referred to the practice as "highly reprehensible." Measured for its harmful effect not only upon the manufacturer whose product has been imitated, but also as it affects the consuming public generally, the act of substitution warrants these accurate and appropriate descriptions.

The act of "substituting" today should be regarded as but one branch of unfair competition. The act of substituting is the act of "passing off" and the general rule has been that where a competitor in dressing his goods has so imitated the goods of another with intent to deceive to the extent that the public generally cannot easily distinguish between them and retailers are placed in a position where they can readily "palm off" the product as the goods of the other, an action will lie against the sale of such products to retailers by producers and by retailers to consumers. (*McLean v. Fleming*, 96 U. S. 245 (1878); *Elgin National Watch Company v. Illinois Watch Case Company*, 179 U. S. 665 (1901); *William R. Warner & Company v. Eli Lilly and Company*, 265 U. S. 526.)

## "Beguilement of Public" Fundamental of Action

No matter what descriptive phrase—"passing off," "palming off," "substitution," "counterfeiting"—is used, and irrespective of a trespass upon any exclusive right of the producer, such activity is part and parcel of unfair competitive practices. In the early legal discussions the court came to recognize that cause of action did not depend upon the exclusive right of the plaintiff, but narrowly conceived that it rested primarily upon "beguilement of the public" as the fundamental of the action.

In *Coats v. Merrick Thread Company*, 149 U. S. 562 (1893), the court said that irrespective of any technical question of trade-mark rights, the defendants had no right to dress their product in such manner as to deceive a purchaser and by such action induce the purchaser to believe he is buying the products of the plaintiff. The court said:

> Rival manufacturers may lawfully compete for the patronage of the public in the quality and price of their goods, in the beauty and tastefulness of their inclosing packages, in the extent of their advertising, and in the employment of agents; but they have no right, by imitative devices, to beguile the public into buying their wares under the impression that they are buying those of their rivals.

To the same effect, see *Italian Swiss Colony v. Italian Vineyard Company*, 158 Cal. 252, 110 Pac. 913 (1910).

In *Samson Cordage Works v. Puritan Cordage Mills*, 211 F. 603 (CCA-6, 1914), the plaintiff had made and sold a high-grade sash cord which was marked with a series of spots arranged spirally about the circumference of the cord, each shaped in the form of a lozenge. An injunction issued restraining the sale of sash cord which in any way would tend to mislead the public into believing that the cord sold by defendant was the plaintiff's product.

In *Pinoleum Company v. Baron*, 121 Misc. 384, 201 N. Y. S. 44 (1923), the plaintiff had produced a remedy and added a green coloring, which additional coloring had no therapeutic value but served solely to make the product distinctive. A competitor imitated by producing a mixture of the same materials, and defendant added a green color which had nothing whatsoever to do with the therapeutic value. An injunction was issued against the sale to retailers by the imitating manufacturer preventing the imitating manufacturer from placing in the hands of the retailer the instrument which made possible the perpetration of a fraud.

However, manufacturers who have imitated or counterfeited have sought escape liability by asserting that the deception in the sale was made by the retailer, over whom the imitating manufacturer had no control.

The competitive relationship exists between manufacturer and imitating manufacturer and, although the imitating manufacturer makes no sale to the consumer, liability is placed upon the imitating manufacturer for enabling the retailer to commit the fraud. The imitator seeks by such plea to overlook the rule of law which asserts that one who induces another to commit a fraud and furnishes the means is equally guilty with the one who actually perpetrates the fraud.

## Example from Restatement of Torts

In the Restatement of Torts the following statement is found in Chapter 35, Section 713: "One fraudulently markets his goods as those of another if, though making no representation himself, he intentionally induces his purchasers so to market them." The example cited in support of the rule is as follows:

> A manufactures a compound of cocoa and quinine for sale. B also manufactures a compound of cocoa and quinine and urges druggists to buy his product, which he offers at a lower price, and to sell it for A's compound when that is called for by customers. B is subject to liability to A.

To the same effect, see *Southern White Lead Company v. Cary*, 25 F. 125 (1885). See also *Oneida, Ltd. v. National Silver Company*, 25 N. Y. S. (2d) 271 at 275, wherein the court said:

> Unfair competition is a species of fraud. . . . the rule is that he who induces another to commit a fraud and furnishes the means is equally guilty with the one who perpetrates the fraud.

The relationship of the imitating manufacturer to the substituting retailer is descriptively set forth in *Von Mumm v. Frash*, 56 F. 830

(1893), where the court described the activities of the defendant, the imitating manufacturer, as follows:

> The defendants make and sell, knowingly, the tools for fraud, and they and the knaves who buy the tools of them intending to use them for the fraudulent purpose for which they were constructed, are co-conspirators, each guilty of the fraud perpetrated in pursuance of the intention with which the tools were made, and this, although the particular person intended to be defrauded is not agreed upon between them.

The liability is the same when the manufacturer places the means within the power of a dealer to deceive the public, and the public is deceived, as where the manufacturer directly accomplishes that result. (*Pennsylvania Rubber Company v. Dreadnaught Tire and Rubber Company*, 225 F. 138 (1915), modified, 229 F. 560 (CCA-3, 1916)). To the same effect, see *Scriven v. North*, 134 F. 366 (CCA-4, 1904), modifying 124 F. 894.

## Where Manufacturer Asserts No Deception of Retailer

For the imitating manufacturer to assert that no deception is practiced upon the retail dealer and that he knows exactly what product he is purchasing carries no weight. The wrong is committed in enabling the dealer to palm off the preparation as the article of the original manufacturer. *William R. Warner & Company v. Eli Lilly & Company*, above. See also *Southern White Lead Company v. Cary*, above. In the *Southern White Lead Company* case, the court said of the imitating manufacturer: "The defendants sell their goods to retail dealers, and it may be that such dealers are not deceived, but they sell to consumers who are or may be deceived."

In *Klotz v. Imperial Perfumery and Barber Supplies*, 298 F. 174 (1924), the court in recognizing an admission by plaintiff that retail dealers would not be deceived, asserted that as long as it could reasonably conclude that the casual purchaser might be deceived and misled, and mistake the defendant's product for the plaintiff's, relief would be granted.

## State Court Conclusion Concurring with Federal Assertions

This is so even though the sale to the retailer is entirely without any misrepresentation whatsoever. (*Kawneer Manufacturing Company v. Detroit Showcase Company*, 240 F. 737 (1917); modified, 250 F. 234 (1918).) The state courts had come to the same conclusion. (*George G. Fox Company v. Glynn*, 191 Mass. 344, 78 N. E. 89 (1906).)

In the case of *Coca-Cola v. Gay-Ola*, 200 F. 720, 722-723, the Court of Appeals for the Sixth Circuit, in enjoining the defendant from copying the color of Coca-Cola in advertising and selling its Gay-Ola imitative drink, said in part:

> Accordingly, we find it recognized by this court that, in a suit for unfair competition, it is not necessary to show that the immediate purchasers were deceived as to the origin of the goods; but even if they thoroughly understand that they are buying the counterfeit, and not the genuine, the manufacturer of the counterfeit will be enjoined from selling it to dealers with the purpose and expectation that it shall be used by the dealers to deceive the consumers . . . . There is no room for it to shift the blame to "tricky retailers" . . . . Defendant is an accomplice, if not the principal, in the trick.

In the case of *Lever Brothers Company v. Eavenson & Sons, Inc.*, 157 Misc. 297, 301, the court, considering unfair competition arising out of the copying of the shape and color of a cake of soap, held:

> The defendant, in reproducing plaintiff's color in combination with the shape and odor of plaintiff's soap, was "motivated by a design to profit by the plaintiff's reputation, investment and advertising, rather than by any utilitarian or functional considerations." *American Chain Co. v. Carr Chain Works, Inc.*, 141 Misc. 303, 308. . . . It is not enough that the distinguishing marks may be identified by a careful and discriminating purchaser. The casual or ordinary purchaser must be protected. A second comer should mark his goods to avoid deception of the public. The acts of this defendant were deliberate and it is clear that defendant's actual purpose was to mislead the public and to induce it to believe that it was buying the plaintiff's product. Actual unfair competition has resulted from the fraud of the defendant.
>
> "That no deception was practiced on the retail dealers, and that they knew exactly what they were getting is of no consequence. The wrong was in designedly enabling the dealers to palm off the preparation as that of the respondent." *Warner & Co. v. Eli Lilly & Co.*, 265 U. S. 526, 530. . . .

In *Smith, Kline & French Laboratories v. Midwest Chemical Development Corporation*, 88 U. S. P. Q. 546, the federal district court judge stated:

> The position of the defendant is this: "The *sole* charge against Midwest is that as a manufacturer, it duplicated certain tablets to a customer's order and supplied those duplicate tablets to its one customer in bottles bearing the customer's name. There is a complete absence of any other activity by Midwest. There is good authority as well as sound reasoning for the view that the act of duplication in itself is not actionable."

The court answered this argument as follows:

> Assuming that the depositions prove conclusively that Midwest has not made any representations to druggists, or in any way induced druggists to "palm off" these pills, the fallacy of defendants' position at once becomes obvious. Unfair competition takes place in many various forms, only one of which is the active solicitation of deception, and that upon which plaintiff relies is what is

popularly termed contributory infringement or contributory unfair competition. A manufacturer, who places into the hands of his immediate purchaser, goods which he knows may cause deception, is liable for unfair competition.

It has been held that it is not necessary to show that a specific purchaser has been deceived when the imitation is sufficiently close that it becomes apparent that confusion will result and lead the public to purchase the imitating manufacturer's goods in the belief that they are the goods of another. (*Von Mumm v. Frash*, above.)

The inquiry by the court is whether the imitation is calculated to deceive or confuse. (*American Chain Company v. Carr Chain Works*, 141 Misc. 303, 252 N. Y. S. 860 (1931).)

In *Enterprise Manufacturing Company v. Landers, Frary & Clark*, 131 F. 240 (CCA-2, 1904), the court, in enjoining the defendant from using plaintiff's distinctive shape and color for coffee and drug grinders, said:

> It is elementary law that when the simulation of a well-known and distinctive feature is so close, the court will assume that defendants intended the result they have accomplished, and will find an intent to appropriate the trade of their competitor, even though in their instructions to their own selling agents they may caution against oral misrepresentations as to the manufacture of the goods. There is evidence to show that purchasers have been deceived as to the identity of these mills, but, in the case of a Chinese copy, such as defendants offer to the public, such proof is hardly needed . . . a court of equity will not allow a man to palm his goods off as those of another, whether his misrepresentations are made by word of mouth or, more subtly, by simulating the collocation of details of appearance by which the consuming public has come to recognize the product of his competitor.

Likewise, in *Thayer Telkee Corporation v. Davenport-Taylor Manufacturing Company*, 46 F. (2d) 559 (DC N. Y., 1930), where the defendant had imitated the style and general appearance of keyboards made by plaintiff, the court said at pages 560-561:

> The only adequate explanation I can find for this almost exact reproduction of nonfunctional features is that the defendant set out deliberately to appropriate the business of plaintiff's customers. And that it is in a fair way to do so, unless prevented by injunction, is reasonably clear from the affidavits submitted on this motion. . . .
>
> I think, therefore, the plaintiff is entitled to the preliminary injunction on the ground of unfair competition. . . .

## Proof of Intent to Deceive

In support of most actions based upon fraud and deception, intent to deceive frequently must be part of the prima-facie proof. However, in unfair-competition cases arising from passing off, the element of

intent need not be proven by direct evidence where it may clearly be inferred from the circumstances. (*Enoch Morgan's Sons Company v. Whittier-Coburn Company*, 118 F. 657 (1902); *Skriven v. North*, 134 F. 366 (CCA-4, 1904); *American Chain Company v. Carr Chain Works*, above.)

In *Scandinavia Belting Company v. Asbestos & Rubber Works*, 257 F. 937 (CCA-2, 1912), the court said at page 962:

> . . . the simulation of the well-known and distinctive features of one's goods may be so close that the court will assume an intent to defraud.

The test applied in the *American Chain Company* case was whether or not the resemblance was apparent and the probability of confusion obvious and, if so, a presumption of an intent to deceive would arise.

In *Wirts v. Eagle Bottling Company* 50 N. J. Eq. 164 (Chancery, 1892), the court agreed that it would not have to attempt to penetrate the secret motive which brought about the act, but that the consequences which flowed naturally and necessarily from the act would be the determining factor. The court reasoned that everyone must be understood to have intended to do just what the natural consequences of the act accomplished. To follow this through to a logical conclusion the court will have to apply its formula and determine the natural consequences of the act. Is it likely that the casual buyer is misled? If so, there is no need of a proof of intention. (*Auto Acetylene Light Company v. Prest-o-lite Company*, 264 F. 810 (CCA-6, 1920).)

## Protection of Ordinary, Casual Purchaser

Courts have held that the imitation would not have to be such as to mislead a careful and discriminating purchaser, but merely enough if it intended to mislead the ordinary and casual purchaser. (*H. E. Winterton Gum Company v. Auto Sales Gum and Chocolate Company*, 211 F. 612 (CCA-6, 1914).

Due regard must be given, some courts have said, to the class of persons purchasing the article and the circumstances ordinarily attending the purchase of that type of article. (*N. K. Fairbanks Company v. R. W. Bell Manufacturing Company*, 77 F. 869 (CCA-2, 1896); *McGill Manufacturing Company v. Leviton Manufacturing Company*, 43 F. (2d) 607 (1930).)

In *N. K. Fairbanks Company v. Dunn*, 126 F. 226 (1903), after describing the activities of an imitating manufacturer as "unlawful" the court went on to say that the retailer had no right to deliver any

product other than the product specifically called for by name and further stated that the customer has the right to receive this specific product when called for, and the customer is not required to take special pains to examine the package when delivered. In this case the court said that when the request is made for a specific product, the retailer must deliver the package specifically called for even if the package sold bears a label which would clearly indicate upon careful examination or even cursory examination by the purchaser that it was not the product specifically ordered.

But what of the situation wherein the outer dress easily recognizable by the consumer has been removed when the product is called for by prescription? In the case of *William R. Warner and Company v. Eli Lilly & Company*, 265 U. S. 526, the Court considered a suit to enjoin the sale of a preparation flavored and colored with chocolate. There it appeared that the defendant sought to avail itself of the favorable repute which had been established by the plaintiff, and defendant salesmen represented to the retail druggist that the defendant's preparation was a good substitute for the plaintiff's preparation.

## Supreme Court Holding in *Warner v. Eli Lilly*

The Court considered in its opinion sales to ultimate purchasers of the product without its formal dress similar to delivery of a product upon prescription which bears only the doctor's name, the patient's name and the directions for use. The Court held that the defendant could manufacture and sell preparations similar to that manufactured by the plaintiff, but must sell it as its own product, recognizing that palming off the product upon the public would in itself be unlawful.

In this case, the Court said at page 530:

> Sales to druggists are in original bottles bearing clearly distinguishing labels and there is no suggestion of deception in those transactions; but sales to the ultimate purchasers are of the product in its naked form out of the bottle; and the testimony discloses many instances of passing off by retail druggists of petitioner's preparation when respondent's preparation was called for. That no deception was practiced on the retail dealers, and that they knew exactly what they were getting is of no consequence. The wrong was in designedly enabling the dealers to palm off the preparation as that of the respondent.

In *Winthrop Chemical Company, Inc. v. Weinberg*, 60 F. (2d) 461 (CCA-3, 1932), druggists substituted an unknown tablet when a well-known brand of a drug was called for by doctors' prescriptions. It was shown that the defendant druggists filled physicians' prescrip-

tions specifically calling for Luminal with other phenobarbitals. The court said at page 463:

> The question before us is simply a case of dishonest deception, and, as said in *Vick Chemical Co. v. Vick Medicine Co.* (D. C.) 8 F. (2d) 49, 50, the "underlying principle of law of unfair competition is to prevent substitution by deception," a principle recognized by this court in *Rosenberg Bros. & Co. v. Elliott* (C. C. A.) 7 F. (2d) 962. In ordinary commercial affairs, "substitution by deception" is wrongful, but, when in the healing art there is "substitution by deception," greed may reach the grade of malice.

In the case of *G. H. Mumm Champagne v. Eastern Wine Corporation,* 142 F. (2d) 499, 501 (CCA-2), in which the court enjoined a champagne producer from imitating the makeup of a competitor's label, Judge Learned Hand asserted:

> . . . when the question is of an injunction, we can find as little warrant for demanding evidence of actual confusion in cases of unfair competition as in those of trade-mark. . . . and, as soon as it appears that the defendant has imitated a make-up, the court will ask no further proof that his purpose to trade upon the plaintiff's reputation is likely to be successful.

The brand itself is representative of the good will and the good reputation of the manufacturer of the genuine product. It would not take many substitutions of an inferior product to create in the deceived consumer, or in the physician whose order has not been filled, a depreciation of the good name and good value which for years has attached to the products of the manufacturer of the genuine article. Good will built up over many years can be destroyed to the end that the consumer and the physician, both of whom have been defrauded, look with suspicion and hesitation not only upon the specific article in which the substitution took place, but upon all of the products of the manufacturer whose name has been blackened by the fraud of the imitating manufacturer or the substituting retailer.

That this is true especially in the case of drugs and medicinal products may be seen in *Sinko v. Snow-Craggs Corporation,* 105 F. (2d) 450 (CCA-7, 1939). In this case, manufacturers of so-called luxury items and specifically, here, a bejeweled addition to the steering wheel of an automobile applied for relief from the activities of a manufacturer who produced a similar bejeweled device. Relief was denied to the complaining manufacturer, the deception in the product of the imitating manufacturer having been held not to impose confusion or deception upon the public. This was so because the public examined the article, noted its artful and graceful design and purchased the bejeweled device and desired to purchase the article because of its

attractiveness. There was no proof that confusion reigned in the public mind. The court, however, distinguished the situation in which a drug or medicine might be purchased, and said at page 453:

> In this connection a comparison might be drawn to a case involving a drug preparation, where the efficiency of the drug depends largely upon the capacity of the maker. In such a case, as distinguished from the instant case, the purchaser would care more about the personality behind the drug than the drug itself.

## Legitimate Manufacturer's Suit for Injunctive Relief a Costly Procedure

What remedies are available? The legitimate manufacturer has a cause of action against the substituting retailers, based on unfair competition. However, such suits for injunctive relief and damages are tiresomely ineffective and expensive. Recognizing that many retailers are honest and scrupulous, we must recognize that in all trades and professions there are a number to whom profit motive is first and foremost and by whom scruples are cast aside to achieve that end. To enjoin a single retailer and recover negligible damages, if any could be proven, would merely mean that across the street or next door, sooner or later, a counterpart or a confederate would undertake the same unconscionable road. This procedure would be too costly both in investigation prior to litigation and in litigation itself to accomplish very much. Many civil actions have been brought against many substituting retailers, but the manufacturer whose product has been imitated and subjected to substitution recognizes the existence of a vicious cycle of continuous litigation.

## Monetary Damages Against Counterfeiting Manufacturer Unsatisfactory, Too

As against the counterfeiting manufacturer whose doors are closed when enjoined and who reopens anew under a different name or corporate guise, monetary damages may be more readily proven than as against the retailer of the product, but again constant and expensive litigation is the result.

In the fields of licensed retailing perhaps more can be accomplished to prevent the impositions and the deceptive practices. A good example of this would be the drugstore. A few states have made some effort to protect against unfair competition by making the act of substitution subject to the criminal laws or subject to administrative

action by the licensing authority with attendant fines, revocations or suspensions. Where, by attempted statutory remedial efforts, the burden is placed upon the prosecuting officials for crime and also upon the administrative licensing body for suspension or revocation of license, the result has been an ineffectual passing of the buck from one official of the government to the other arm of the government. Though the federal laws, especially wherein food, drugs and cosmetics are involved, grant a remedy other than civil, the great cost of investigation and prosecution would not warrant strict enforcement. Certainly, in the licensed fields as against retailers, it might be accomplished by the administrative determination and penalties.

Some leaders in the field of the licensed trades, businesses and professions seek integration of all members of the trade, business or profession under association sponsorship and provide for restraint of unfair competitive practices by canons of ethics.

## Possible Solutions—Infrequently Employed

If an injunction could be broad enough to go beyond, prospectively, the imitating manufacturer to his subsequent business and corporate relationships and if provision could be made for punitive damages in addition to the damages which normally flow and which are more difficult of proof, it would serve as a great deterrent to those following in the footsteps of a convicted or enjoined substitutor or imitator. Too few times has the contempt power been employed. Too infrequently, when the contempt charge has been proven, has the court been made to realize the gravity of the offense.

No utopian solution has as yet been devised and with morality and ethics in business, trade or profession digging to a new low in these times, the problem continues to be unsolved. **[The End]**

## TRADE REGULATION—PRICE DISCRIMINATION—GROCERY PRODUCTS

An *FTC* complaint against a grocery company charged with knowingly receiving price discriminations on grocery products has been dismissed without prejudice. The hearing examiner ruled that the complaint did not properly allege violation of Section 2 (f) of the Clayton Act in failing to charge that besides knowingly receiving discriminatory prices, the respondents knew that they were not within defenses afforded sellers by other provisions of Section 2. (Final order released September 25, 1953.)—CCH TRADE REGULATIONS REPORTS, ¶ 11,513.

By JOHN J. HORAN

**Addressing ABA's Division of Food, Drug and Cosmetic Law August 25, the Advisor on Legal Matters to the American Delegation to the Sixth World Health Assembly Discussed:**

# A WHO International Pharmacopoeia

IN THE EARLY PART of this year, great concern was expressed in the United States over a program undertaken by the World Health Organization to adopt international common or generic names for all useful drugs. The principal criticisms of the program were directed to its lack of a well-defined procedure, and of adequate notice and opportunity to be heard to those whose legitimate rights were seriously affected. We found that our concern was shared by other countries and that the WHO was quite willing to discuss the problem and take whatever steps were necessary to correct it. The recent Sixth World Health Assembly adopted a well-defined procedure which provides for adequate notice and opportunity to comment on or object to proposed names and which defines the scope of the program. This has been reported on at length elsewhere; those interested may wish to read an article by the speaker in this month's issue of the *United States Trade Mark Reporter*. I would like to discuss with you a companion activity of the WHO—the selection of standards, strengths and dosage forms for drugs to be published as an *International Pharmacopoeia*.[1]

All concerned with drugs are familiar with the *United States Pharmacopoeia* and the *National Formulary*, publications which establish official drug standards in the United States. Those engaged in international commerce will also be familiar with at least some of the national pharmacopoeias of other countries.

The word "pharmacopoeia" is defined in my desk edition of Webster as: "A book describing drugs, chemicals and medicinal prepara-

[1] The official title is in Latin—*Pharmacopoea Internationalis* — abbreviated as "Ph. I."

tions, especially one issued by official authority and recognized as standard." We believe that in modern usage the term pharmacopoeia clearly means on official compendium of legally binding standards.

The WHO is a specialized agency of the United Nations operating under a constitution which is an international treaty subscribed to by 80 countries, including the United States. An international pharmacopoeia—published by the WHO and hence, presumably, approved by 80 countries—would appear to be a significant new factor in world medicine.

The WHO Constitution (Article 2k) authorizes the organization to propose to its member states "conventions, agreements and regulations and to make recommendations with respect to international health matters"; and also to adopt by majority vote in the assembly regulations concerning "standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce." The WHO has chosen the least formal alternative in its pharmacopoeial program and considers that the drug standards published in the *International Pharmacopoeia* are "recommendations."

The objective of the program is stated to be "the unification of pharmacopoeias," that is, world-wide agreement on drug standards and nomenclature, and elimination of the differences now existing among the national pharmacopoeias. A tremendous amount of disinterested work has been done in the preparations of monographs by an expert committee appointed by the WHO, composed of men outstanding in ability and experience in pharmacopoeial work, who serve without remuneration. It is with the greatest trepidation that a lawyer undertakes to comment on a technical program into which so much expert work has gone for the attainment of a most desirable objective. I venture to do so because of the conviction that certain aspects of the program are in need of examination and discussion.

The program is of substantial significance to American nationals although it will not affect our domestic law. It may strongly affect the American drug and pharmaceutical industry, as well as that of other countries, in the manufacture and marketing of drugs in international commerce. Many customers will undoubtedly request or require that drugs conform to *International Pharmacopoeia* standards. The health officials of countries which do not possess a national pharmacopoeia may reasonably be expected to refer to the *International*

*Pharmacopoeia* in setting drug standards for imports; I would particularly anticipate this in the Latin-American markets. Countries may adopt the *International Pharmacopoeia in toto* as their national pharmacopoeia; Israel announced its intention of doing so at the last assembly, and it has been reported that India and Egypt have indicated similar intentions.

How, then, is this vitally important program handled? The WHO appointed in 1947 an Expert Committee on the Unification of Pharmacopoeias. Dr. Rasmussen of the Danish Pharmacopoeia, one of the original members of the committee, reported in 1951:[2]

> It was desired that the number of members should be limited as far as possible, as it was thought that a smaller commission could finish the work more easily and quickly than a larger one, which always moves very slowly.

There were, therefore, only six members on the original committee. In 1950, a broader "panel" was created, which comprised 30 experts. However, the bulk of the work continues to be done by an expert committee with from six to ten members drawn from the panel. This committee, acting on a volunteer basis in the time the members can spare from their regular full-time activities, has drawn up drug standards and decided on drug nomenclatures. Most of the work has been done in committee meetings held at Geneva. The standards are not submitted to member states as proposals; there is no publication of or discussion of them outside the committee. The standards so prepared are being published by the WHO as its *International Pharmacopoeia*. Volume I has been published, Volume II is in galley proof, and an Addendum is near completion. Full coverage of all important drugs is expected; in fact, drugs will be included for which standards have not yet been adopted by the national pharmacopoeias.

This WHO procedure is in sharp contrast to that used in the preparation of the *United States Pharmacopoeia* or *National Formulary*, where the work of preparing standards is participated in by all those who are interested in and will be affected by them, including the medical profession, pharmacists, government officials and the drug and pharmaceutical industry. Standards are established only after publication of proposals and public hearings on them. In contrast, the standards set forth in the *International Pharmacopoeia* to apply throughout the world as prepared solely by the expert committee.

[2] H. Baggesgaard Rasmussen, "Fifty Years Endeavor to Create an International Pharmacopeia," *F. I. P. Bul. 24 e Am.*, p. 20, 1951.

The views of those whose rights and businesses will be affected are not sought or considered. In fact, they are specifically excluded from consideration since, as Dr. Miller—the American member of the committee—reports, the proposed standards are deemed "confidential" and are not to be circulated for comment.

One may well wonder whether the WHO will develop adequate and practical standards for the new drugs without reference to those organizations whose research and production staffs have discovered or developed the drugs and who may fairly be presumed to be most familiar with them. We feel there can be no question that the WHO should not proceed in so important an undertaking without notice, hearing or opportunity to be heard to those who will be affected.

Those who feel that such notice or hearing is unnecessary point out that the *International Pharmacopoeia* is not legally binding and consists solely of WHO recommendations which it may formulate in the manner it deems most convenient; that *International Pharmacopoeia* standards become legally binding only when adopted by member states; and that United States nationals can claim no right to be heard on decisions by other countries as to what drug standards they shall enforce.

## Where Legal Concern Begins

The adoption of drug standards by a particular country may be something with which United States nationals have no legal concern. The publication of standards, whether legally binding or recommended, by the WHO is something with which United States nationals are very much concerned. We are participants in and supporters of the work of the WHO and are, and should be, interested in its decisions as to international drug standards.

The WHO cannot escape responsibility for the effects of its decisions by labeling them "recommendations." The *International Pharmacopoeia* will and is intended by the WHO to affect the international marketing of drugs. The WHO must bear responsibility for the results it intends. Moreover, whatever their legal status, it seems to us that these standards are not published as "recommendations."

The United States has already pointed out to the WHO that the name *International Pharmacopoeia* implies a set of legally binding standards rather than a group of recommendations. It is to be expected that those who know that the *United States Pharmacopoeia*, the *British*

*Pharmacopoeia*, the *Danish Pharmacopoeia*, etc., are compendia of official drug standards will assume that the WHO *International Pharmacopoeia* is a similar volume of greater authority. It is not surprising therefore to find the WHO itself so referring to it.

Here is the way the *International Pharmacopoeia* is described in a leaflet and order form published by the WHO:

> The *Pharmacopoea Internationalis*—the first international pharmacopoeia—Volume I of which appears now in English and French and will shortly be available in Spanish also, is a work of historic importance, produced with a view to fulfilling the desire, long felt by pharmacists and physicians throughout the world, for the establishment of internationally recognized standards and nomenclature for pharmaceutical preparations in universal use. . . .
>
> To all concerned with the prescribing and dispensing of pharmaceutical preparations, the *Pharmacopoea Internationalis* will be of immense interest. *Laying down, as it does, international standards for drugs,* this work will undoubtedly help "to promote and protect the health of all peoples."

One must read carefully through a five-page preface to the *International Pharmacopoeia* to find on the fourth page in the second sentence of the first full paragraph a statement that the *International Pharmacopoeia* "is not intended to be a legal pharmacopoeia in any country unless adopted by the pharmacopoeial authority of that country." It seems clear that a purchaser of drugs is not likely to notice, much less be persuaded by, this single sentence in a five-page preface. It is doubtful that any disclaimer will be effective in the face of the claim to official standing implied in the name *International Pharmacopoeia*.

*International Pharmacopoeia* standards will be considered official ones to which manufacturers should conform. Where the standard differs from that in the *United States Pharmacopoeia*, it may also be felt that the *International Pharmacopoeia* bearing the imprimatur of the WHO and its 80 member countries is the better authority.

In actual fact, under the present procedure, the standards to be published in the *International Pharmacopoeia* represent the views of the small group of experts selected by the WHO who act in a personal capacity, do not purport to represent the views of their home country and reach their decisions after informal discussions and correspondence among themselves. *To label such standards as a WHO International Pharmacopoeia appears to us misleading.*

The *International Pharmacopoeia* will, as a practical matter, create problems in the United States in those instances in which the *International Pharmacopoeia* standard varies significantly from that established in the United States by law. The importance of open discussion

of proposed WHO standards to minimize or eliminate such conflicts should be immediately apparent. The American drug and pharmaceutical industry should not be faced by the WHO with a *fait accompli* in the form of standards adopted and published without notice.

A specific example which has been called to my attention may serve to illustrate the problem. A foreign customer recently informed an American drug manufacturer that penicillin it had sold him did not conform to WHO standard. The company immediately retested the material and found that it was well above the United States standard set by the Food and Drug Administration. The WHO standard is not available to the company, since it is to be published in Volume II of the *International Pharmacopoeia* and is still confidential. The company's foreign distributor forwarded to it some information which indicates that the *International Pharmacopoeia* standard embodies requirements for penicillin blood level tests which are not required in the United States and which it is felt here are impractical as a routine requirement. There are other variations between the *International Pharmacopoeia* and United States standards.

## First Indication of Problems to Come

The American manufacturer doesn't know whether there are good reasons for the variations, since it has had no opportunity to consider or discuss them. The company is still awaiting information from its customer as to the exact nature of the WHO standards and tests. It does know that the health officials of the country concerned have stated that its penicillin will not be admitted into the country unless the company shows conformance to *International Pharmacopoeia* standard. The manufacturer is concerned with this marketing problem; it is even more concerned at the implication, which we believe totally unwarranted, that its goods may not conform to the highest practicable standard. We feel that this is but the first vague indication of problems to come because of the inadequacies we have indicated in the WHO pharmacopoeial program.

We recognize the outstanding experience and the eminence of the WHO expert committee, and the unselfish effort they have devoted to this work. We feel sure they will agree that those who will have to deal with the WHO standards in the market place may be forgiven for pointing out what they feel are serious deficiencies in the procedure the WHO has been following.

We would emphasize the fundamental unfairness of reaching decisions without proper notice to, and consideration of, those whose rights and interests will be affected, particularly in activities such as the *International Pharmacopoeia*, which are of a regulatory nature. We would also urge that the WHO give greater consideration in this area to the practical effects of its decisions, for it is the practical result which determines the price and quality of drugs.

We are in a new era of international activity, and the World Health Organization is a part of that activity which is of particular interest and importance to the food, drug and cosmetic industry. The constitution of the WHO provides for and the WHO will undoubtedly undertake a wide range of activity which will affect us in the United States. To cite one example in addition to those discussed today, the Sixth World Health Assembly convened at Geneva requested the WHO executive board to "look into the problem of standardizing laboratory tests on food additives because of the increasing use of these substances." It is important that we keep informed on the activities of the WHO and similar international legal bodies with the same diligence that we follow our domestic legislatures and administrative agencies. I suggest to you that we may have been somewhat remiss in thus far failing to do so.

The prompt and vigorous action taken by the WHO to correct the shortcomings of its nonproprietary name program has made a profound and highly favorable impression in the United States. It has indicated that the WHO is concerned with the maintenance of democratic procedures in its programs. The approach of the WHO secretariat to the problem was in no sense arbitrary, but was on the contrary marked by a willingness to give fair consideration to problems presented to them. We feel sure that we shall find the same reasonable approach by the WHO to any other problems arising out of its activities which are called to its attention.

We informed the WHO secretariat at Geneva in May that we anticipated that difficulties would arise in connection with the *International Pharmacopoeia* somewhat similar to those encountered in the nonproprietary name program. I urge on you now the importance of interested United States nationals examining the WHO pharmacopoeial program and bringing any criticism of it to the attention of our government and of the WHO as promptly as possible.

**[The End]**

# Section 403 (d)—

## CONTAINERS SO MADE, FORMED OR FILLED AS TO BE MISLEADING

By JOHN C. MARTIN

**This Is a Research Paper Written by a 1952-1953 Fellow in the Graduate Program in Food and Drug Law at New York University, in Cooperation with The Food Law Institute**

ALTHOUGH the federal reporters contain relatively few reports of decisions arising under Section 403 (d) of the Federal Food, Drug, and Cosmetic Act, comment is in order because of the importance of the provision as a means of protecting the public from deception. The annual reports of the Food and Drug Administration through the years emphasize this importance. For example, in the year 1940, the Administration reported [1] that 89 seizures of food had been made under this provision of the Act. During the years 1945 through 1947, 108 seizures were made and four criminal prosecutions were instituted.[2] Recent reports [3] would seem to indicate that violations are on the decline, and thus it appears that the provision is accomplishing—to a large extent—its very important purpose of preventing consumer deception.

It is the design of this paper briefly to trace the history of the section and analyze the reported cases arising under it.[4] Other problems presented by the provision will then be discussed and an attempt will be made to determine its true application. It should be noted at the outset that although the topic is concerned only with the mis-

[1] See Food Law Institute Series, *Administrative Reports 1907-1949*, p. 975.

[2] Cited at footnote 1, at p. 1289.

[3] The 1949 report revealed there were five seizure actions: See reference cited at footnote 1, at p. 1392. The 1950 and 1951 reports contain no mention of the subject.

[4] The reader's attention is directed to another article on this subject: Franklin M. Depew, "The Slack-Filled Package Law," 1 FOOD DRUG COSMETIC LAW QUARTERLY 86 (1946). This paper attempts to avoid repetition.

branding of foods under 403 (d), much of what is said will be applicable under analogous sections that pertain to drugs and cosmetics.[5]

## Section 403 (d): Its Enactment

Section 403 (d) provides:

> A food shall be deemed to be misbranded—. . .
> (d) If its container is so made, formed, or filled as to be misleading.[6]

The Federal Food and Drugs Act of 1906 [7] had no provision aimed at deceptively made, formed or filled containers that was analogous to the present section. An amendment to the 1906 Act, known as the Gould Amendment, was passed in 1913 in an effort to require that the consumer be adequately informed as to the contents of containers. It provided that an article would be deemed to be misbranded in the case of food:

> Third. If in package form, the quantity of the contents be not plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count . . . .[8]

The Gould Amendment proved to be inadequate in protecting purchasers from deception because a true statement of the contents in conformance with the amendment did not prevent misleading where, for example, the contents were estimated by the physical appearance of the container rather than by the label statement of weight.[9]

An amendment was introduced in the House in 1919 to correct this defect, and was debated and passed [10] but failed to meet with Senate approval. Several like amendments [11] were passed by the House in later years and were rejected by the Senate until the present section was enacted, along with other sweeping changes, in 1938.

The committee report [12] accompanying the 1919 amendment quoted a statement submitted by the Department of Agriculture to the effect that purchasers are deceived by containers that are only partly filled despite the fact that the correct weight may be stated in accordance

[5] These are Section 502 (i) (1) of the Act as to drugs and Section 602 (d) as to cosmetics. The wording of these sections is identical with that of 403 (d). There is no analogous provision dealing with devices.

[6] Federal Food, Drug, and Cosmetic Act Sec. 403 (d), 52 Stat. 1043 (1938), 21 USC Sec. 343 (d) (1946).

[7] 34 Stat. 768, 21 USC 1 (1906).

[8] Act of March 3, 1913, Ch. 117, 37 Stat. 732. The amendment contained a proviso: "*Provided, however*, that reasonable variations shall be permitted, and tolerances and also exemptions as to small packages shall be established by rules and regulations made in accordance with the provisions of Section three of this Act."

[9] See, for example, Committee on Agriculture, 66th Cong., 1st Sess., H. R. Rep. No. 438, p. 3.

[10] H. R. 10311 as amended passed the House December 8, 1920, 60 *Congressional Record* 59 (1920), 66th Cong., 3d Sess., debated 60 *Congressional Record* 51-59 (1920).

[11] H. R. 762, 68th Cong., 1st Sess.; and H. R. 8, 71st Cong., 2d Sess. See also footnote 16.

[12] H. R. Rep. No. 438, cited at footnote 9.

with the requirements of the net-weight amendment (the Gould Amendment). The markings were said to be an insufficient means of apprising the purchaser of the actual amount of food purchased.[13] The committee report further quoted the statement as saying:

> The second type of fraudulent package which in the opinion of the department, should be dealt with by way of further amendment to the food and drugs act is that which is contrived to give the purchaser a false impression as to the quantity, quality, size, kind or origin of the food contained therein.[14]

In 1930, a provision known as the Canned-Foods Amendment or the McNary-Mapes Amendment became law.[15] It was aimed at slack-filled containers to some degree because it provided for the setting of standards of fill (as well as of "identity" and "condition") for canned goods.

Provisions directed against deceptively made, formed or filled containers were introduced in the Seventy-third, Seventy-fourth and Seventy-fifth Congresses in substantially the same form, and finally enacted by the Seventy-fifth Congress.[16] The considerations given these provisions will be referred to during the course of this paper as an aid in determining the meaning of the present section.

## Cases Arising Under 403 (d)

In *U. S. v. 738 Cases . . . Jiffy-Lou Vanilla Flavor Pudding*,[17] the government had proceeded against a dessert product in a libel action alleging a violation of Section 403 (d) in that the container was so filled as to be misleading. The district court, sitting without a jury, found as a fact that the commodity filled:

> . . . only approximately about 55% of the exterior container without allowance for space required by the inner removable package . . . .[18]

The court, in finding the container not so filled as to be misleading within the meaning of Section 403 (d), stated that the section:

> . . . applies only to a container so made, formed or filled as to be misleading in fact.[19]

Findings of fact were set forth by the court to support its conclusion that the evidence did not show the container to be misleading as a matter of fact. The findings stated among other things:

> That the container used is of a size which is recognized by the general public as a standard size for this and similar commodities and contains a standard

[13] Cited at footnote 12, at p. 3.
[14] Cited at footnote 12, at p. 3.
[15] Act of July 8, 1930, Ch. 874, 46 Stat. 1019.
[16] For example, S. 1944, 73d Cong., 1st Sess.; S. 2000, 73d Cong., 2d Sess.; S. 2800, 73d Cong., 2d Sess.; S. 5, 74th Cong., 1st Sess. and 2d Sess.; and S. 5, 75th Cong. 1st Sess. and 3d Sess., which became law.
[17] 71 F. Supp. 279 (DC Ariz., 1946).
[18] Cited at footnote 17, at p. 280.
[19] Cited at footnote 17, at p. 281.

amount of ingredients sufficient to produce and make a standard amount of finished product—there is no relationship between the size of the container used and factors and reasons causing the public to purchase the commodity involved.[20]

In *U. S. v. Cataldo*,[21] the government had appealed from a dismissal of its libel against boxes of candy alleged to be misbranded by slack-filling within the meaning of 403 (d). The candy itself occupied less than 50 per cent of the total package. The court of appeals, in affirming the dismissal of the libel, stated that whether or not over 50 per cent of space in a particular package of candy was slack-filling was a question for the district court to decide.[22] Under Rule 52 (a) of the Federal Rules of Civil Procedure findings of fact could not be set aside unless clearly erroneous, and the court could not say that such was true in the case before it.[23]

Although affirming, the court took occasion to point out errors of the district court in requiring evidence that the containers had been "palmed off" on the public and that the markings would likely mislead the average purchaser. The court of appeals stated:

> Whether or not the articles in question had been "palmed off" on the public or whether or not the markings on the package were proper markings were questions not relevant to the issue in this case . . . .[24]

The case of *U. S. v. 116 Boxes . . . Arden Assorted Candy Drops*,[25] is the final reported case arising under the section. Here, small boxes of candy drops containing approximately 33 per cent of air space were seized. As in the previous cases, the government libel action was dismissed. Judge Wyzanski stated that the question whether the package is misleading is a question of fact.[26] He also stated that the Act prohibits the shipment of a package of candy which is in fact so slack-filled as to be misleading, even if the package correctly states the weight of the contents.[27] He found that under the circumstances a consumer would not be misled: that the ordinary purchaser of this type merchandise would know the product to be machine packed and expect only as many pieces as could conveniently be packed in a standard carton by machine.[28]

The cases discussed are in accord on the proposition that whether or not the container is so made, formed or filled as to be misleading is a question of fact in the particular case. There can be no hard

[20] Cited at footnote 17, at p. 280.
[21] 157 F. (2d) 802 (CCA-1, 1946).
[22] Cited at footnote 21, at p. 804.
[23] Cited at footnote 21, at p. 805.
[24] Cited at footnote 21, at p. 804.
[25] 80 F. Supp. 911 (DC Mass., 1948).
[26] Cited at footnote 25, at p. 913.
[27] Cited at footnote 25, at p. 913.
[28] Cited at footnote 25, at p. 913. Another case might be cited here at the conclusion of the case discussion: *U. S. v. 149 Gift Packages*, 52 F. Supp. 993 (DC N. Y., 1943). This case was not concerned with the meaning of the section.

and fast rule, therefore, as to what would constitute slack-filling.[29] The mere fact that a package is only partially filled with food will quite clearly not per se constitute a violation of the section.

The *Jiffy-Lou* case is significant because it brings to light the importance of the factors causing the consumer to purchase. The court stated that there was no relationship between the size of the container used and the factors and reasons causing the public to purchase the commodity involved [30]—that is, the product was bought, the court found, for the purpose of producing a certain amount (one pint) of the finished product and, presumably, if this purpose were satisfied there would be no misleading. However, the container used was of a size recognized by the general public as a standard size for such commodities. If the container were much larger than standard size it might be found as a fact that the size of the package induced purchases and, therefore, the section might be violated.[31]

It is not necessary to show that the container has actually been "palmed off" on the public. It is sufficient to show that the container would be likely to mislead the ordinary purchaser of the particular type of merchandise.[32] Further, the government need not prove that the markings of a container are misleading, as the district court in the *Cataldo* case mistakenly assumed. However, it is thought that proper markings may prevent the container from being misleading in fact in a particular case—that is, the legislative history shows the section was designed to reach situations where the consumer was likely to be misled *despite* truthful labeling.[33] If it can be shown that the consumer is not likely to be misled *because* of truthful labeling that adequately informs him of the contents, it would seem to be contrary to the purpose of the Act to declare the article misbranded.[34]

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[29] *Cataldo* case, cited at footnote 21, at p. 804.

[30] *Jiffy-Lou* case, cited at footnote 17, at p. 280.

[31] Thus, a trade correspondence (TC-161) of March 14, 1940, stated: "We . . . fully appreciate the point you raised in regard to packages of this type being designed to furnish material for standard amounts of finished dessert. However . . . we cannot share your conclusion that . . . eliminates the possibility of deception under Section 403 (d)."

[32] *Arden* case, cited at footnote 25, at p. 913.

[33] See, for example, Dunn, *Federal Food, Drug, and Cosmetic Act*, p. 244, S. Rep. No. 361, 74th Cong., 1st Sess., by the Committee on Commerce (to accompany S. 5). The report stated in part: "Packages only partly filled create a false impression as to the quantity of food which they contain despite the declaration of quantity of contents on the label." See, to same effect, S. Rep. No. 493, 73d Cong., 2d Sess., Dunn, work cited, p. 118.

[34] The purpose is to prevent deception. See Dunn, work cited, at pp. 118, 135, 244, 1072, 1173 and 1274. Congress did not consider the question of adequate labeling in regard to 403 (d). Cf. Depew, work cited, at p. 95.

Truthful labeling as to the contents may be inadequate to prevent misleading, however, even assuming the information is sufficiently conspicuous. For example, where the label states the weight of a product, such as a cereal, it means little to the housewife, and the size of the package is still an important factor in inducing the purchase.[35] Similarly, an indication on the label of the number and size of a particular food would not prevent misleading if the consumer would expect the container to be filled to a greater extent than it is by such number and size and purchased the food accordingly. However, if in a particular case it can be shown that the product is bought solely by number or weight, for example, then a sufficiently conspicuous and adequate label statement of the number or weight might prevent the likelihood of the purchaser being misled. This would be because the appearance of the container would no longer be an indication to the purchaser of what he is getting.

A difficult problem exists where the container is so filled that it is likely to mislead consumers in the ordinary sense of the word, and yet the container cannot be made to contain more food under good manufacturing processes. What is the solution under the section? It is clear from the legislative history that Congress did not intend to outlaw containers that were not completely full but that were filled as far as practicable under good manufacturing processes.[36] Settling, shrinkage and expansion after original filling were also not intended to cause a violation of the section.[37] During committee hearings on the bill in the Senate an addition to the section was turned down that would have expressly made allowance for reasonable variations and tolerances due to subsequent shrinkage or expansion and for discrepancies due to natural or other causes beyond

[35] This example was considered in Senate hearings before the Committee on Commerce on S. 2800 in the 73d Cong., 2d Sess. See Dunn, work cited, at pp. 1173-1174.

[36] S. Rep. No. 493, cited at footnote 33, by the Committee on Commerce (to accompany S. 2800). Dunn, work cited, at p. 118: "This provision is not intended to authorize action against packages of foods which are filled as full as is practicable under good manufacturing practice." To the same effect, see S. Rep. No. 361, 74th Cong., 1st Sess., by the Committee on Commerce (to accompany S. 5). Dunn, work cited, at p. 244; also a substitute report to accompany S. 5: S. Rep. No. 646, 74th Cong., 1st Sess., by the Committee on Commerce, Dunn, work cited, at pp. 479-480.

Further, in Senate hearings on S. 2800 in the 73d Cong., 2d Sess., we find the following statement by the then Chief of the Food and Drug Administration: "Mr. Campbell. . . . now there can be in my judgment, no conviction of the manufacturer where the shrinkage is due to causes which the manufacturer cannot control." See Dunn, work cited, at p. 1174. See also p. 1174 for an indication by Mr. Campbell that the courts would insist upon a reasonable construction of the Act and therefore there was no need to adopt a proviso concerning reasonable variations, and p. 1274 in regard to recesses in packages necessary in machine operations.

[37] See footnote 36.

reasonable control in good commercial practice.[38] It was decided not to include such a provision, for the courts would have difficulty in applying it due to its broad language.[39] Walter G. Campbell, then Chief of the Food and Drug Administration, expressed the belief that such a provision would multiply lawsuits indefinitely, and that the provision was not needed because a reasonable interpretation would be given to the section without it.[40]

In the *Arden* case, Judge Wyzanski emphasized facts showing the necessity of the air space in good manufacturing practice and concluded that the ordinary purchaser would expect such space in the packages due to machine packing.[41] Although the "ordinary purchaser" in this case would appear to be a rather extraordinary person, Wyzanski believed the standard of such person to be set by Congress for the purposes of Section 403 (d). Thus, he stated:

> It is the expectations of a person who has that common degree of familiarity with our industrial civilization which furnish the standard which Congress intended to be applied.[42]

It does not appear from the legislative history that Congress intended such a standard to be applied. A better approach would seem to be that where the apparent deception could not be avoided under good manufacturing practice the container would not be misleading within the meaning of the section. Thus, misleading through causes unavoidable in good manufacturing practices would be in the nature of an exception under the section. The same would be true where there was subsequent shrinkage or settling. It is hoped that the language of the *Arden* case will not be used by subsequent courts to lower the amount of protection given to consumers by elevating too high the standard of the "ordinary purchaser."

## What Is Slack-Filling?

The term "slack-filled" has been used a great number of times, and Section 403 (d) is aimed in part at slack-filled containers.[43] However, there does not appear to be a clear answer as to what is meant by the term or when the section is violated because of slack-filling. Where the container is partially filled with food and the

[38] Dunn, work cited, at pp. 1173-1174. The hearings were on S. 2800 in the 73d Cong., 2d Sess. The proviso was referred to as the "Dunn Bill."

[39] Dunn, work cited, at pp. 1174-1175.

[40] Dunn, work cited, at p. 1174.

[41] *Arden* case, cited at footnote 25, at p. 913.

[42] Cited at footnote 25, at p. 913.

[43] Rep. No. 152, 75th Cong., 1st Sess., by the Committee on Commerce (to accompany S. 5), contained a statement that the Act prohibits "slack-filling." Dunn, work cited, at p. 692; See also pp. 32, 89, 118, 135, 161, 277, 308-309, 681, 742, 1043, 1071, 1173 and 1274 for similar statements.

remainder is empty, the answer is clear. Also, where the remainder of the container is filled with cardboard, wax or some other nonfood material, the purchaser has not obtained the amount of food expected and the section would no doubt apply. Where a container is filled with a mixture of canned tomatoes and water, the question becomes closer because there is no space of nonedible material. Is the container "slack-filled" and therefore possibly "so . . . filled as to be misleading"? Canned tomatoes with excessive water have often been cited as an example of "slack-filling" by the administrative agencies charged with enforcing the 1906 Act.[44]

Where the container is packed, for example, with peaches and excessive peach juice, the whole container is filled with food but not in the expected proportions. If this is slack-filling could we not then say that if a jam product contained a less proportion of fruit and more sugar and water than expected it would be slack-filled and violate the section? It would seem that the answer to the problem must lie somewhere between questions of identity and containers with only food and empty space. Where a product is bought as an integration of its known ingredients, it is difficult to see how the container can be said to be slack-filled or partially filled merely because the proportions of the ingredients are unexpected.

The distinction between the food expected and the amount of packing media would seem to be the sensible solution to many of the problems, and the relative amount of ingredients should not be controlling—that is, a container would be slack-filled if it contained more than the expected amount of packing media (and, therefore, less food solids), even though there were no space in the container filled by nonedible or non-nutritious material. It should be noted that the government has apparently been following this theory in promulgating standards of fill under Section 401 [45] of the Act.[46]

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[44] See annual reports for 1912, 1914, 1918, 1919, 1920, 1923 and 1924 at pages 262, 325, 380, 404, 430, 558 and 585, respectively, of the reference cited at footnote 1—especially, at pp. 262, 380, 430 and 558.

[45] Federal Food, Drug, and Cosmetic Act, Sec. 401, 52 Stat. 1046 (1938), 21 U. S. C. Sec. 341 (1946).

[46] The standards of fill have been promulgated regulating the amount of packing media and fruit solid, even where the media is fruit juice. The standards of fill relate to standards of identity, and the amount of "optional ingredients" and "optional packing media" are regulated. See, especially, 21 C. F. R. 27.2, 27.12, 27.22 and 27.32. Also, in regard to standards of fill, see 21 C. F. R. 27.42 (fruit cocktail), 21 C. F. R. 36.3, 36.6 (shellfish), 21 C. F. R. 51.2 (vegetables) and 21 C. F. R. 53.42 (tomato products). Also, note Statement of General Policy or Interpretation 21 C. F. R. 3.1: "Section 403 (d) of the Act provides. . . . It is our opinion that these sections apply to canned oysters if water, brine, or liquid draining from oysters during processing, replaces a quantity of oysters which should be added to fill the can."

## Effect of Promulgation of Standards of Fill

If a container complies with the standard of fill as set under Section 401 it may nevertheless be subject to being proceeded against under 403 (d). There is no indication that the container would be immune in such a case, and the regulations promulgated under Section 401 provide that no provision of the regulations shall be construed as affecting the application of any provision of the Act.[47] It is thought that, as a policy matter, the Administration would be reluctant to proceed in such a manner, but might well do so where there is a pressing need.

It should be noted that under Section 403 (h) (2)[48] if the container bears a statement in proper form that it falls below the standard of fill, it will not be deemed to be misbranded for failing to conform to the standard of fill. Such a container could still be proceeded against under 403 (d) if purchasers would likely be misled as they could easily be despite the statement that the container is slack-filled.[49]

## Deception by Other than Slack-Filling

So far, we have dealt chiefly with containers that might be misleading because they are slack-filled. An article may also be deemed to be misbranded under 403 (d) because the container is so made or formed as to be misleading and also so filled as to be misleading in other ways than by slack-filling. There have been no reported cases interpreting these forms of misbranding, but it is clear from the legislative history how the section would be applied in certain instances.[50] For example, containers with false bottoms would be so made or formed as to be misleading.[51] Containers so shaped as to deceive the purchaser as to the size of the contents or having colored cellophane "windows" that would make the contents appear better

[47] 21 C. F. R. 10.0 (c).

[48] Federal Food, Drug, and Cosmetic Act, Sec. 403 (h) (2), 52 Stat. 1047 (1938), 21 U. S. C. Sec. 343 (h) (2) (1946).

[49] Under the regulations, 21 C. F. R. 10.2 (b), the statement must read: "Below Standard in Fill." It might be found as a fact that a purchaser would not expect, say, a 10 per cent fill.

[50] Statement in Senate in regard to S. 2800 by Senator Copeland, 73d Cong., 2d Sess.: "We likewise had before us specimens of plain or water noodles wrapped in yellow cellophane to make them look as if they were rich in egg." See Dunn, work cited, at p. 161. Other examples considered at various points in the legislative process included deceptive filling by so packing that the portion displayed gives an erroneous impression of the identity or quality, Dunn, work cited, at p. 244; false bottoms in containers, and boxes to make eggs look of the same size, Dunn, work cited.

[51] Dunn, work cited, at p. 244.

are other examples.[52] Where better-grade products are placed on top of the pack and the inferior beneath, we have an illustration of a container "so filled as to be misleading" by means other than slack-filling. If the purchaser is likely to be misled as to the quantity, quality, size, kind or origin of the food within a container by the way it is made, formed or filled, the section would be applicable.[53]

Despite the fact that the government has lost the cases discussed under Section 403 (d), the provision stands as an important weapon against consumer deception. Truthful labeling in conformance with the Act may not sufficiently inform the purchasing public, and the deception may not be covered by other sections of the Act. However, containers may be likely to mislead because of make, form or fill and yet not be violative of the section because the make, form or fill is necessary under good manufacturing practices.[54] Therefore, it is suggested that the advisability and possibility of regulations that would force the disclosure of the contents of containers more adequately be considered. Perhaps a statement of the percentage of fill would be possible. Also, illustrations on the container of the size of the contents, warning against shrinkage and possibly the drawing of a conspicuous line showing the degree of fill might help prevent consumer deception.[55] Certainly, the honest manufacturer has no objection to the consumer knowing what is in the container to be purchased. Where discrepancies occur through good manufacturing practices, therefore, the consumer would still be protected to a large degree by adequate labeling.

Wise administration of Section 403 (d) and industry cooperation are of course very important, and provide the key to the solution of many problems.[56] However, a sound construction of the section by the courts will also play a large part in determining the application of the section in the future. **[The End]**

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[52] Dunn, work cited, at pp. 161 and 244.

[53] This is not an exhaustive list of factors that might cause misleading. H. R. 10311 (see footnote 10) contained such a list.

[54] Note here that the *Arden* case disagrees in theory, as Judge Wyzanski reasoned that the "ordinary consumer" is not misled in such a case.

[55] Reference should be made to a discussion by W. R. M. Wharton, then Chief of Eastern District, Food and Drug Administration, American Management Association Marketing Series No. 38, "Planning the Package" (1940). Excerpts from the article are reprinted in the CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 3043.26. We find this statement: "Where the bottle itself is not deceptive, some manufacturers have recently endeavored to correct possible deception of the packages by printing a facsimile or reproduction of the bottle on the principal carton label. The Administration has indicated that if this is done in such a way as to show the exact size of the bottle, possibility of deception will be materially reduced."

[56] Past events indicate that this has been the practice. See Depew, work cited, at pp. 89-90 (1946).

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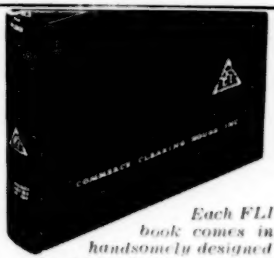

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